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The Latex Condom

Recent Advances, Future Directions



Editors

Erin T. McNeill

Caroline E. Gilmore

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FAMILY HEALTH INTERNATIONAL

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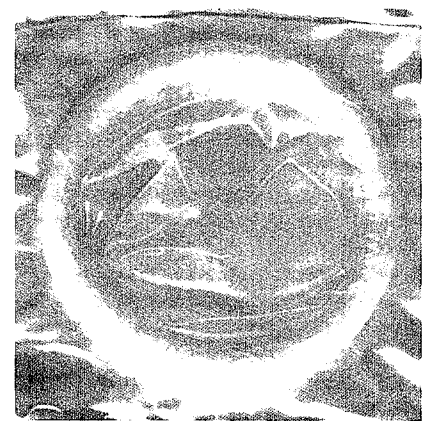


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Why a Monograph on Latex Condoms?

by JoAnn H. Lewis

Condoms in various forms have been with us for centuries. The use of barriers covering the penis to protect against disease dates back to at least 1350 BC, and for pregnancy prevention at least to the 16th century AD. Since the 1930s, latex condoms have been available to prevent both pregnancy and sexually transmitted disease (STD), but in most parts of the world they have never been widely used. When forms of contraception that were not coitally dependent became available in the 1960s and 1970s, the use of condoms declined. Beginning in the 1980s, however, the worldwide epidemic of STDs, including HIV/AIDS, prompted a renewed interest in latex condoms, which, to date, remain the most effective method of preventing disease transmission during sexual intercourse.

The rediscovery of condoms for disease prevention has led to an explosion in research and technical knowledge during the past decade and the first substantial modifications in manufacturing of condoms since the 1930s. Along with the technical improvements in the product, research has contributed to a better understanding of the behaviors that influence whether and how condoms are used, and the extent to which user behaviors and technical product attributes interact to determine effectiveness. Sadly, the great improvements in condom design and reliability are not widely known. Consumers and service providers alike continue to lack confidence in the condom's ability to prevent pregnancy and disease.

While perceived unreliability is often a problem, a host of other issues present greater

barriers to overall acceptability of condoms. Many people do not believe they are at risk of STD/HIV. Others do not like the feeling of a condom or worry about their partner's reactions to suggesting condom use. Some are embarrassed by, or lack skills in, adding condom use to sexual activity. Communication between sexual partners is minimal in many cases, contributing to non-use and higher STD rates. Also, cultural and political norms often reinforce negative perceptions of condoms and tend to limit their availability. The most important obstacle to more widespread and consistent use of condoms, however, appears to be that consumers do not like them.

The aim of this monograph is to draw together the wealth of information that now exists on multiple aspects of latex condom manufacturing, quality assurance, performance in human use, acceptability and user behaviors – and the interrelationships among these issues. The monograph focuses on the product, its attributes and how attributes affect human use. Providing a comprehensive review of all the behavioral and programmatic issues that relate to condom use is beyond the scope of this monograph. We briefly review the major issues regarding behavior change and condom acceptability, focusing on the interaction between people and product. We explore the remaining gaps in knowledge about latex condoms, describe several non-latex alternatives for men and women that are in development or have recently become available, and propose research priorities for the future. We hope that researchers, manufacturers, regulatory officials and public health professionals

who promote and provide condoms will find the information in these pages useful.

The impetus to produce a monograph on latex condoms came from an experts meeting convened by Family Health International (FHI) in May 1996. The meeting brought together representatives from research, industry, regulatory agencies and the donor community to assess needs and set priorities for future research on latex condoms. In particular, the experts scrutinized the issue of whether laboratory measures of condom reliability can predict condom performance in human use. The consensus of the meeting was that relating laboratory-based measurements of quality assurance with human use remains problematic. Even so, we know a great deal about the technical merits of latex condoms and an ever-increasing amount about consumer use behaviors.

The experts proposed a publication that would summarize state-of-the-art information from the various disciplines involved in the production, quality assurance, behavioral research and promotion of latex condoms. This would be a first step in determining future research needs, while also serving to address the gaps in knowledge regarding condoms. Since a significant portion of the work that is reported here has been carried out by FHI, its presentation is influenced by the perspectives that have evolved at FHI. We also acknowledge the importance of the work on condoms done by others and trust that we have adequately represented their contributions in this volume. While we summarize the research findings of other groups, these results do not necessarily reflect the views of FHI.

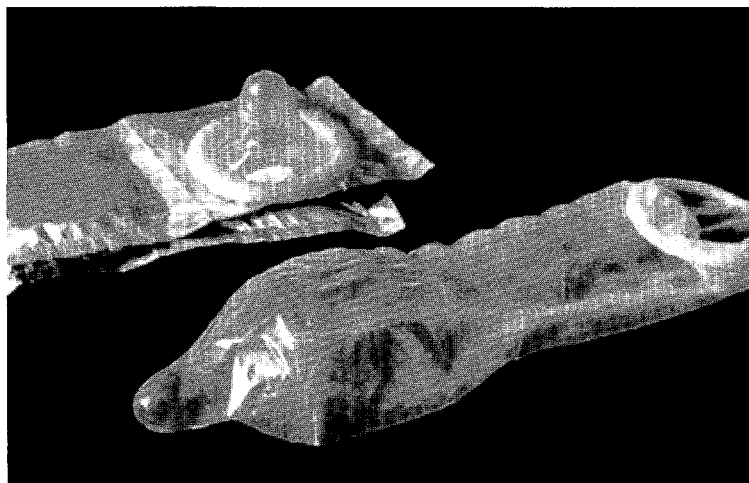
Beginning in the mid-1980s, FHI, with support from the U. S. Agency for International Development (USAID), undertook a

program of research to apply the same scientific rigor to the study of condoms that had been applied to the study of other contraceptive methods. The research carried out by FHI and other agencies, such as the Program for Appropriate Technology in Health (PATH), has provided new information on the physical characteristics of the latex condom and on behavioral aspects that influence whether and how condoms are used.

During the past decade, manufacturers of latex condoms have continued to make improvements in the product based on new insights provided by the growing body of research on a wide range of issues and based on changes in purchase specifications of major buyers. Condoms now on the market are manufactured more consistently, have better formulations of latex, have incorporated a wide range of design modifications to improve both acceptability and functionality, and are subjected to pre-marketing quality assurance. Improvements in packaging have minimized potential damage to the product prior to use. Currently available condoms, if packaged and stored correctly, will maintain their quality for five years or more. If used consistently and correctly, they rarely fail and are highly effective in preventing pregnancy and sexually transmitted disease.

In the chapters that follow, we first examine recent research on the effectiveness

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Alex Trembl

of latex condoms in preventing pregnancy and STDs. Since understanding why people do or do not use condoms is critical, we devote Chapter 2 to consumer attitudes and preferences, summarizing what is known about product acceptability issues. Behaviors and characteristics of condom users are often primary factors in condom effectiveness, as demonstrated by the studies summarized in Chapter 3. Chapter 4 discusses recent advances in the manufacture of latex condoms, focusing on improvements in latex formulation, packaging and reducing health-related problems related to latex and other allergies.

In Chapter 5, we move into the more technical area of product testing and standards for condom production, and what these standards mean for assuring product quality. Chapter 6 discusses the thorny issue of whether laboratory testing can predict condom performance in human use. Chapter 7 describes new non-latex products, such as the recently marketed polyurethane female condom and non-latex condoms for men that are now in development. Finally, Chapter 8 synthesizes the major messages in the monograph, presenting 10 reasons why we should have confidence in condoms, 10 priority areas

for future research, and essential public health messages for condom users.

Substantial strides have been made over the past decade in improving understanding of condoms and their use. This synthesis of new information and knowledge, combined with suggestions for future research, could lead to further improvements in latex condoms and to increased consumer acceptance of the condom. Increased product reliability and acceptance may, in turn, lend a higher level of confidence among the millions of people worldwide who either use or should use condoms to protect their health. It might also assist public health professionals in discouraging behaviors that lead to condom failure and encouraging behaviors that enhance product performance. The public health benefits of correct and consistent condom use are clear. Public health officials and service providers have an urgent responsibility to reinforce confidence in condoms as a contraceptive method and to promote their use for disease prevention.

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Pregnancy and STD Prevention

by Paul J. Feldblum

Condoms are the only contraceptive method proven to reduce the risk of all STDs, including HIV. Thus they can be used as a dual-purpose method, both for contraceptive and prophylactic reasons. Also, they can be used as part of a dual-method regimen, in which another method is used primarily for contraception, and the condom is used specifically for disease prevention.

Studies have found that consistent and correct use of condoms is by far the most important factor in preventing both pregnancy and disease, compared to failure of the device through breakage or slippage. Pregnancies reported with condom use are due primarily to inconsistent and incorrect use, not to defective condoms. Failure of the condom itself is rare. Research has shown that exposure to semen is nearly always due to non-use, with a very minor portion due to breakage during use and virtually none due to holes resulting from the manufacturing process. (FDA)

This chapter summarizes the effectiveness of latex condoms in preventing pregnancy and STDs, and the ability of latex condoms to block passage of genital fluids and their constituents between sex partners. It discusses various factors that influence contraceptive effectiveness and can lead to disparate estimates of pregnancy rates. The chapter shows that even among couples with one partner infected with HIV, consistent condom use results in a near-zero risk of HIV transmission.

Factors that Influence Pregnancy Rates

Results of studies of the contraceptive effectiveness of condoms vary considerably, as

they do for other coital-dependent contraceptive methods. Twelve-month life table pregnancy rates for condom users have ranged from 2 to 14 per 100 women. (Hatcher) This compares with about 85 per 100 couples who would conceive a pregnancy in a year if not using contraception. These rates are slightly better than for other barrier methods but not as good as for hormonal methods or IUDs.

Variations in reported pregnancy rates, for condoms as well as other coital-dependent methods, derive from several factors: correct and consistent use, the capacity to conceive, and the frequency and timing of intercourse. (Steiner) In addition, the study methodology can affect the rates.

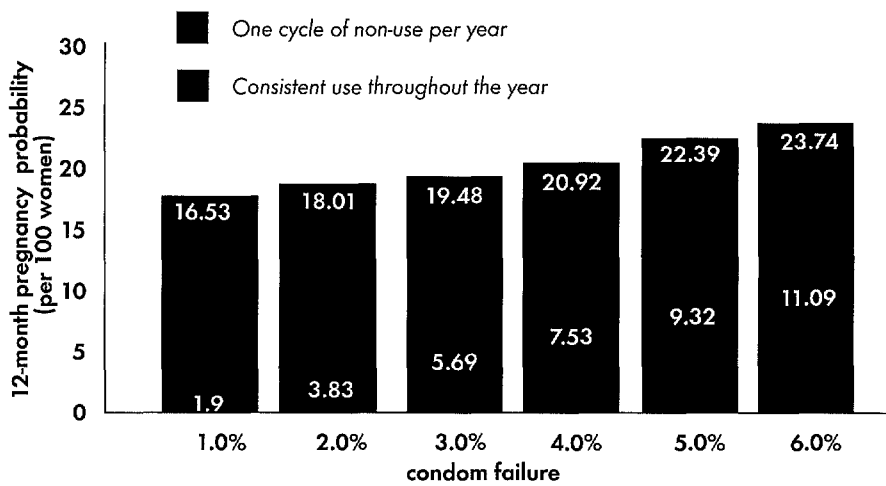
Correct and Consistent Use. Contraceptive use results in different pregnancy rates among different types of study participants (single or married, adults or teenagers, educated or less educated, etc.). Much of this variation stems from differences in the consistency and correctness of using the device, and leads to consideration of two terms: perfect use and typical use pregnancy rates. Providers and users need to become familiar with both perfect use and typical use pregnancy rates — estimates of optimal and average pregnancy risk — to ensure informed choice of family planning methods.

The lowest pregnancy rate follows from *perfect use*. This refers to the experience of those who report using the method exactly as it should be used (correctly) and at every intercourse (consistently). Estimated pregnancy rates during perfect use of condoms is 3 percent at 12 months. (Trussell) The pregnancies that do occur in reported perfect use are

due either to condom failure or to inaccurate reports from study participants.

A recently completed randomized controlled trial of latex versus male plastic condoms reported pregnancy rates for couples who used condoms at every intercourse, called "consistent use" rates. The six-month consistent use rates were 1.2 per 100 women using latex condoms and 2.6 per 100 women using plastic condoms, which would equate with 2 to 4 pregnancies per 100 women at 12 months. (A Nelson)

Figure 1-1 Pregnancy Probability, Consistent and Inconsistent Condom Use*



Most frequently cited is the pregnancy rate in *typical use*: how many unintended pregnancies would occur in the first year among 100 couples using a method. This rate can include perfect and imperfect use. The pregnancy rate during typical use can be much higher than during perfect use, especially for a coital-dependent method like the condom. Multiple studies can help identify the range of typical pregnancy rates and point out sub-groups that are particularly well or poorly suited to use a method.

Many assume that pregnancy rates cited for condom users correspond to the proportion of condoms that fail, equating, for example, a 10 percent typical pregnancy rate with 10 percent condom failure. In fact, condom failure is rare. Condom failure refers to the device breaking or slipping off completely during intercourse. The higher typical-use rates are due primarily to inconsistent and incorrect use, not to condom failure. Research has shown that only a minority of users report condom failure. Also, condom failure does not invariably lead to pregnancy.

Two models demonstrate the crucial importance of consistent condom use to contraceptive effectiveness. In both cases, inconsistent condom use has a far greater impact on increased pregnancy rates than condom breakage, regardless of the cause of condom breakage.

One model suggests that failing to use a condom during even a single fertile cycle has more impact on annual probability of pregnancy than does higher condom breakage. With condom breakage rates of 2 percent, if there is one cycle of non-use out of 13 cycles in the year, the expected annual probability of pregnancy jumps more than four-fold, from 3.8 to about 18 per 100 women. In contrast, if the condom breakage doubles from 2 percent to 4 percent, but condoms are used all the time, the annual probability of pregnancy approximately doubles from 3.8 to 7.5 per 100 couples (see Figure 1-1).* (Dominik)

A second model, developed by the U.S. Food and Drug Administration (FDA), estimates the average semen exposure per coital act due to condom non-use, condom breakage and holes in condoms used. Semen exposure due to breakage was assumed to occur in about 2 percent of devices used. Semen exposure due to holes in the latex membrane was estimated from earlier *in vitro* work. (Carey et al; Lytle) Given the relatively low frequency of breakage,

* The model assumes that the probability of pregnancy during a single unprotected act during the fertile period is 0.15, that there is one act per fertile period, that there are 13 cycles per year, that a condom that breaks provides no protection, and that a condom that does not break is 100 percent effective. (Dominik)

and the size and frequency of holes in the devices, exposure to semen was found to be nearly always due to non-use, with a very minor portion due to breakage and virtually none due to holes. (FDA)

Capacity to Conceive. The inherent fecundability of a couple (the capacity to become pregnant), which is influenced by various physiologic factors, is also crucial to the observed pregnancy rates. For example, within the reproductive years, older persons are less fertile on average than younger. Women with irregular, or extremely short or long, menstrual cycles may have hormonal abnormalities and hence be less fecund. People with a history of STD may be infertile, such as women who have had pelvic inflammatory disease. The dimensions of fecundability may be difficult to measure, however, and there is no single index that encapsulates the concept. Nevertheless, it is likely to contribute to observed variability in pregnancy rates across different user populations.

Frequency and Timing of Coitus. Conception can occur only during a few specific days during the menstrual cycle. The more often a couple has intercourse, the more likely they will do so during these days and be exposed to pregnancy. Ideally, the frequency and timing of intercourse must be accounted for in the calculation of pregnancy rates. Therefore, coital logs are an important design feature of any condom effectiveness study. The condom study with the lowest reported pregnancy rate was conducted among older users with (presumably) a lower coital frequency, and with a lower likelihood of conception than younger users. (Potts)

Given the strict inclusion criteria in most clinical trials, cohorts are likely to differ from the general population in the above factors that affect pregnancy rates. An inclusion criterion for parity, or one for a threshold coital frequency, may be associated with greater fecundity and a higher pregnancy rate, for instance. Conversely, frequent follow-up

and counseling of study participants would tend to improve compliance, which would depress pregnancy rates. Thus, the results of clinical studies must be generalized with care.

Study Methodology. Apart from behaviors and characteristics of the study cohorts, there are also methodological sources for the variation in pregnancy rates. (This is true for other methods as well as condoms.) The timing of data collection is important. A retrospective study with interviews about past contraceptive behavior and pregnancy history will almost certainly yield different results than a prospective study that requires regular clinic visits and pregnancy testing. Most condom effectiveness data are from retrospective studies. This shortcoming will be rectified by prospective studies recently completed or currently under way. (A Nelson)

Different computations can yield widely differing pregnancy rates. A Pearl index is the ratio of the number of pregnancies observed in a study divided by the total number of years that all study participants have been studied. Pearl rates decline over the length of a study because participants likely to conceive a pregnancy tend to do so early, leaving more consistent and correct (or less fecund) users in the study.

The life table method is the preferred method for calculating effectiveness because each month of the study is treated as a separate calculation. The monthly proportions are multiplied together to arrive at a cumulative proportion conceiving, usually within six or 12 months of beginning the method. Only participants still in the study in a given month are considered at risk of pregnancy during that interval, but participants who become pregnant, leave the study for other reasons, or are lost to follow-up are all accounted for, since the results from all months are included. Unlike the Pearl index, life table pregnancy rates vary from zero to 100, rise with the length of the study, and can take into account other reasons for leaving the study besides pregnancy.

Effectiveness of Latex Condoms against Disease

Unlike pregnancy prevention, in which the unintended outcome can only occur during a portion of the menstrual cycle and during the reproductive years, disease transmission can occur during each and every act of intercourse for all persons, regardless of age. Despite this heightened risk, inconsistent or non-use of condoms is common even among persons at very high risk of STD exposure.

Numerous studies have been conducted on the risk of STDs in condom users. These studies usually present a summary relative risk measure, i.e., a comparison of the disease risk in condom users versus the risk in non-users. For each relative risk estimate, a value of less than 1.0 indicates protection, or a lower risk in the condom group. Virtually all clinical and epidemiological studies have found substantial reductions in the risk of disease among condom users. (Cates; Daly)

It appears that latex condoms, with or without the use of spermicides, are effective in preventing disease. The presence or absence of spermicides does not appear to increase protection against STDs. FHI data show that cervical and vaginal STD rates among female sex workers using plain lubricated or spermicidally lubricated condoms were approximately equal. (Roddy)

As with pregnancy prevention, using condoms consistently results in better

protection from disease. Population-level data from Thailand show that a condom promotion program that reportedly led to near-universal condom use during commercial sex is associated with steep declines in the nationwide numbers of bacterial STD cases, (Hananberg) and reduced HIV prevalence in male Thai military conscripts. (KE Nelson)

The most convincing data on risk factors for HIV infection come from prospective studies of serodiscordant couples, those where one partner is infected and the other is not. In these situations, regular sexual exposure to an infected partner is known, and more accurate record-keeping on condom use is usually possible than in retrospective surveys. (Feldblum) Three recent studies of heterosexual serodiscordant couples have compared rates of HIV seroconversion (where the uninfected partner becomes infected) in couples using condoms with varying consistency (see Table 1-1).

Two extremely important conclusions are supported by all three studies. First, with consistent condom use, the HIV infection rate among the uninfected partners was less than 1 percent per year. Second, in situations where one partner is definitely infected, inconsistent condom use can be as risky as not using condoms at all.

In a multi-center Italian study that followed 305 sexually active seronegative female sexual partners of HIV-infected men for a

Table 1-1. HIV Infection in Prospective Studies of Serodiscordant Couples

Study	N*	% Consistent Users Infected	% Inconsistent Users Infected	% Non-users Infected
Saracco	305	1.7	14.5	10.1
de Vincenzi	256	0.0	9.9	not reported
Deschamps	177	2.4	13.3	14.4

* Couples that remained sexually active

median of 24 months, 3.9 infections occurred per 100 person-years (py). (Saracco) The HIV incidence was reduced by 84 percent in women who always used condoms compared with women who used them inconsistently or never (rate ratio 0.2; 95% confidence interval [CI] 0.1-0.5).^{*} Of the 171 women who always used a condom, 1.7 percent became infected. The percent infected was higher among those using condoms some of the time (14.5 percent of 55 women), compared with those who never used condoms (10.1 percent of 79 women).

A multi-country European collaborative study enrolled 378 seronegative regular partners of HIV-infected men or women; 256 of the couples continued to have vaginal or anal intercourse. (deVincenzi) About one half of the couples used condoms at every intercourse, and no seroconversions occurred among these couples (95% CI 0-1.5 per 100 py). Nearly 10 percent of the 121 couples who used condoms inconsistently or not at all seroconverted, an HIV incidence rate of 4.8/100 py (95% CI 2.5-8.4). These infections occurred even though 50 percent of the inconsistent users reported using condoms at least half the time.

In a Haitian serodiscordant couples study, 63 percent of couples ceased sexual activity soon after enrollment. The HIV seroconversion rate among the 177 couples who remained sexually active was 5.4 per 100 py. (Deschamps) The infection rate was 1.0 per 100 couples who always used condoms (2.4 percent of 42 couples), compared with 6.8 per 100 couples who used condoms inconsistently or not at all (rate ratio 0.1). As in the Italian study, there was almost no difference in the risk of infection between inconsistent users and non-users. Of the 45 inconsistent users, 13.3 percent became infected; of the 90 non-users, 14.4 percent became infected.

These three studies show that consistent condom use is extremely effective against HIV transmission. Even with regular exposure to infection, self-reported consistent condom

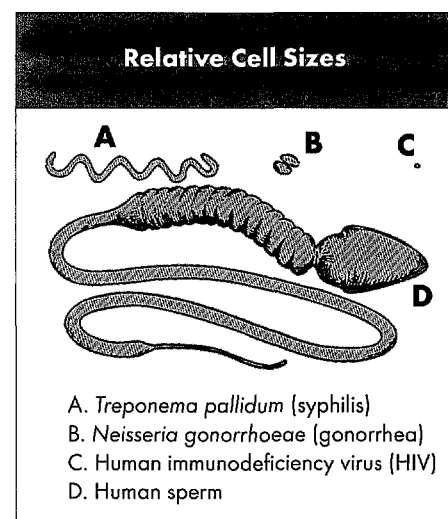
users have a near-zero risk of HIV. However, among these serodiscordant couples, inconsistent condom use carries considerable risks of HIV infection, since exposure to infection is guaranteed at every unprotected intercourse. In this sexual context, inconsistent condom use offers little protection against HIV, compared with non-use.

In most circumstances, however, condom use, even if inconsistent, has considerable public health benefit. Unlike serodiscordant couples, the majority of persons at risk of HIV infection do not have a guaranteed risk of infection with each sexual encounter. Hence, most persons will reduce their risk of infection by using condoms even inconsistently. This is because some of the non-use of condoms takes place with uninfected partners, and some condom use takes place with infected partners.

Latex Membrane Permeability

Latex condoms are virtually certain of blocking passage of genital fluids and their constituents between sex partners. The organisms that condoms are designed to block range in size from spermatozoa, about 0.003 millimeters (mm), or 3000 nanometers (nm) in largest diameter, through the STD pathogens: *N. gonorrhoeae* (800 nm), *C. trachomatis* (200 nm), HIV (125 nm) and hepatitis B virus (40 nm).

To be effective for disease prevention, defects in latex membranes must not allow small pathogens to pass through otherwise intact devices. Scanning electron microscopy of latex condoms reveals pits and imperfections but no pores that penetrate the entire membrane. (Kish) Laboratory studies generally have found that viruses do not pass through intact latex condoms, even when the devices



^{*} "Rate ratio" is a measure of relative risk. "Confidence interval" is a measure of the precision of a measurement, in this case, the rate ratio.

are stretched and stressed. (Conant; Katznelson; Minuk; Van de Perre; Reitmeyer; Judson)

Two FDA teams have devised laboratory tests to simulate body fluid transfer to test the permeability of latex condoms. Carey and colleagues used fluorescing plastic microspheres 110 nm in diameter, approximately equivalent in size to HIV. In addition, the degree of acidity, surface tension, viscosity, temperature, pressure, geometry and time were all considered and controlled in the study of 89 condoms. Although 29 condoms showed evidence of leakage, the estimated amount of fluid crossing the membrane was 0.1 microliter or less, corresponding to 0.01 percent of typical ejaculate, an amount that would be expected to be virus-free in an HIV-infected man. (Carey) Thus, even with pinhole leakage in some devices, the authors estimated that condom use would decrease exposure to HIV 10,000-fold. They concluded from this simulation that the latex condom offers extremely reliable protection against HIV but does not totally eliminate the risk. (Carey)

The second FDA study tested 470 latex condoms using a virus of about 30 nm in diameter (i.e., about four times smaller than HIV), controlling viscosity, surface tension and pressure. With 12 condoms (2.6 percent), minute amounts of viral particles went through the latex membrane, a median of 4×10^{-3} ml. (Lytle) But the study estimated that actual use conditions would allow 100-fold less viral penetration, because of the assumptions made in the laboratory. Like the Carey study, this laboratory simulation found that latex condoms are extremely effective but not absolutely perfect barriers to viral passage.

Conclusion

Laboratory research shows that intact latex condoms form a barrier that is nearly always impermeable to spermatozoa and pathogens. It follows that consistent and correct use of latex condoms substantially reduces the twin risks of unintended pregnancy and STDs, although those risks are not zero.

It is important to remember the difference between perfect use and typical use in studies reporting pregnancy rates. Another important message is that spermicidally lubricated condoms do not seem to improve protection against cervical and vaginal STDs over non-spermicidally lubricated condoms.

Two important public health messages emerge from the research reviewed here. First, the latex condom is an extremely reliable device in terms of its ability to block the passage of sperm or pathogens. Second, consistent and correct use of condoms is far more important in preventing both pregnancy and disease than the failure of the device through breakage or slippage. It is important to remember that a 10 percent pregnancy rate, for example, does not mean the condoms failed 10 percent of the time. These pregnancy rates occur primarily because of inconsistent and incorrect use, not condom failure, which is rare.

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Acceptability of Condoms — User Behaviors and Product Attributes

by Alan B. Spruyt
and William R. Finger



Beryl Goldberg

Many men and women prefer unprotected intercourse or using another contraceptive method rather than using a condom. Among currently married women of reproductive age, only 5 percent use condoms for contraception worldwide, and only 3 percent in less developed regions of the world, according to United Nations estimates of contraceptive use. (UN)

National surveys generally do not record condom use among unmarried persons and in sexual activity outside of marriage, arenas that are critical for disease prevention. Some recent Demographic and Health Surveys (DHS) have

found that men report higher condom use than women and that men report higher condom use with partners other than spouses. In the Zimbabwe DHS, for example, of those men having sex in the last four weeks with their spouse, 12 percent had used a condom, while men having sex with other partners reported using a condom 60 percent of the time. (Hulton) Nevertheless, one analysis estimated that overall condom use is less than half of what is needed to protect the health and lives of men and women. (Liskin)

This chapter reviews some of the surveys that have identified why people do not use condoms. It then discusses briefly the most

important issues that affect condom acceptability in terms of behavior change in the AIDS era, and summarizes research on the potential impact of condom design and manufacturing innovations on consumer acceptability.

The most frequent reasons people give for not using a condom relate to the following issues: lack of sensation or interrupted sexual pleasure; psychological and social factors, including couple communication and assumptions that condoms are for use in extramarital relationships and with prostitutes; lack of availability of condoms, including policies that prohibit condom distribution to youth; and lack of confidence in the reliability of condoms themselves. To make condoms more acceptable and more widely used, all of these issues should be addressed.

Factors affecting the acceptability of condoms can be thought of as a series of concentric circles that interact with each other — from the individual at the center to the couple, the health-care system, the community and the entire world. An individual's knowledge, attitudes, habits, perceptions, awareness of the need and other internalized factors are critical to condom use. But what forms those belief systems and determines individual behavior? The dynamics between sexual partners play a crucial role and depend on many factors, such as whether sex is with a regular partner or not, whether the couple talks about sex and protection against disease and unwanted pregnancy, and whether sex is voluntary for both parties.

At the community level, many programmatic issues are involved, from counseling in health-care systems to condom logistics and distribution systems. National as well as local policies about condoms affect acceptability, as do attitudes and pronouncements about condom use by parents, church leaders, peers, entertainment figures, political leaders and others. Worldwide priorities for AIDS prevention campaigns influence the messages that communities receive and how they respond.

Persuading people at risk of STD/HIV to use condoms is one of the primary strategies of AIDS prevention programs throughout the world. In general, lessons from AIDS prevention campaigns show that product attributes play a minor role in initial condom acceptance compared to strategies that influence an individual's perception of the importance of condom use. Once a person starts using condoms regularly, product attributes may play a more significant role in continued use. Condoms are most effective if used consistently, which requires sustained behavior change. If preferences regarding product attributes can encourage consistent condom use over a sustained period of time, choices among various types of products may be important.

Some research has examined the relationship between consumer acceptance and condom attributes, including lubricants, width, thickness, formulation, shape and materials. This research, summarized below, has generally compared user preferences between a standard latex condom design and a condom with a different attribute. The studies were not designed to evaluate whether product design modifications would affect the prevalence of condom use. Even so, when findings suggest that a significant proportion of participants prefer a condom that is not widely used or available in a given population, making that new type of condom available might increase overall condom use.

Reasons for Non-Use

Studies in many parts of the world indicate that couples do not use condoms for many reasons, including fear of partners' reactions/partner opposition, lack of confidence in the product, decreased pleasure, and not perceiving the risk of disease.

Among 620 women interviewed at a family planning clinic in Jamaica, respondents gave three primary reasons for non-use of condoms. Most often the women said they did not need

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protection in addition to their primary contraceptive method because they were not at risk of STDs. Also, condoms were uncomfortable or decreased pleasure, and their partner was opposed to using condoms. (Spruyt)

A study in Uganda interviewed 130 women, half of whom were infected with HIV. "I have never used a condom and would not like to use one," said one young woman in the survey, because she incorrectly thought "it is risky since sperm can pass through the condoms." The view of the husband was also a critical factor. An HIV-positive woman, age 21, who knew that condoms can prevent HIV transmission, said, "Though I have never used a condom, I would use it if my husband is the one who suggests it." Many women also said they feared that if they requested their husbands use a condom, their partners would think that they were prostitutes or unfaithful. (Rwabukwali)

Among 544 men attending STD clinics and a university health service in Australia, about one out of five were no longer using condoms. The major reasons were that his partner(s) were using another contraceptive, he was not sexually active, he thought his partner(s) did not have an STD, and he did not like how condoms felt. (Richters)

In a nationally representative sample of more than 3,000 U.S. men interviewed about condoms, the most frequently cited negative reactions were: reduces sensation, requires being careful to avoid breakage, requires withdrawing quickly, embarrassing to buy, difficult to put on, often comes off during sex, embarrassing to discard, shows you think partner has AIDS, and makes partner think you have AIDS. (Grady)

Another U.S. study of 652 sexually active people found that 61 percent reported not using a condom with their last sexual partner. Low perceived risk of HIV infection was the main reason given, although most did not know enough about their partner to be sure. (Kusseling)

Focus groups in China's most populous province of Sichuan discussed condom use

among 106 people, divided into male condom users, wives of condom users, men whose wives used other contraceptives, and women who were using other forms of contraception. Many participants thought of condoms as troublesome to use, easy to forget and causing a decrease in sexual satisfaction. (Lin)

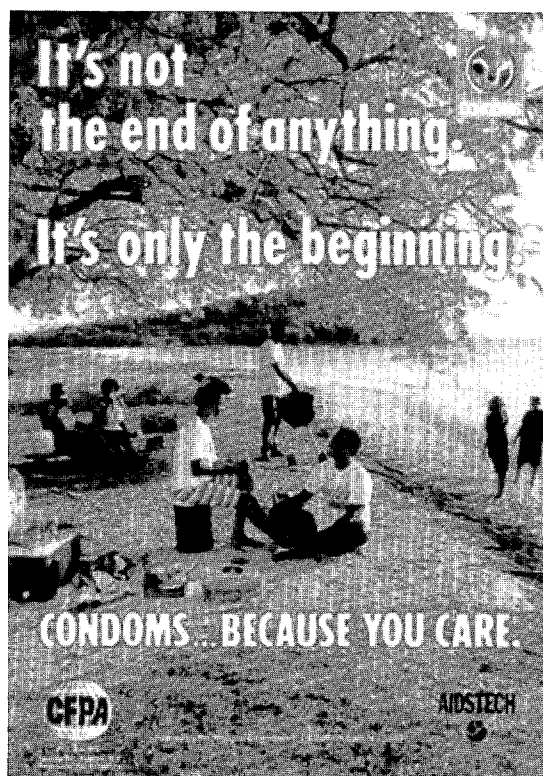
Changing Behavior

The lessons learned from AIDS prevention efforts in the last 10 years offer a wealth of information about condom acceptability. A full discussion of behavior change and condom promotion is beyond the scope of this monograph. However, a brief review of these issues helps put the importance of condom product attributes into a full context of condom use.

Behavior change involves many issues. People need knowledge, such as what causes HIV transmission, what types of sexual behaviors can put a person at increased risk of infection, and how to change those behaviors. People have to change attitudes, such as acknowledging their risk of infection. And, they need skills, such as how to communicate with a partner about the importance of using a condom. To take the next step and begin using condoms, people must find condoms readily available and affordable.

Important factors for large-scale changes in behavior regarding condom use include promotional campaigns, reaching men and effective counseling. Promotional campaigns in particular have resulted in sharp increases in condom use in many countries. For example, in the early 1980s, there were less than 1 million annual condoms sales in sub-Saharan Africa. (PSI) In 1996, there were nearly 20 million condoms sold a year in Ethiopia alone. Experts in Africa see the pattern of large-scale condom sales across sub-Saharan Africa as evidence of major behavioral change among African men. (Finger)

By far, the most dramatic factor in this increased condom use is the international funding for AIDS prevention campaigns, and specifically, the expansion of social marketing



An AIDS prevention poster.

programs in all regions of the world.

In Haiti, for example, an expanded social marketing campaign took condom sales from 250,000 per month in 1992 to 540,000 a month in 1996. In Nepal, sales went from 465,000 condoms a month in 1994 to about 1 million a month in 1997.

Social marketing is the application of commercial marketing techniques to achieve a socially beneficial goal. It involves market research, message testing, mass media advertising, consumer education, effective use of news media and public relations, product promotion at the point of purchase, increased access to products and affordable pricing. Generally, the condoms are subsidized so that prices can be kept low enough for users to buy them but high enough for merchants to have an incentive to sell them. In Nepal, for example, a sales force concentrated on the highways into the country from India, a known route for HIV transmission. From 1994 to 1997, the number of outlets stocking condoms increased from three pharmacies to 56 retail outlets, including pharmacies, tea shops, liquor shops and others.

The climate for mass media messages about AIDS and condoms has substantially improved since the early 1990s. When Archbishop Desmond Tutu, the prominent and well-respected clergyman in Africa, endorsed condom use on South African television, it affected not only social norms about condom use but also media access. For years, social marketers had battled to gain access to mass media. As recently as 1990, for example, the word "condom" was prohibited in advertising by the government of Kenya. Today, more explicit advertising is permitted in many parts of the world.

Not only does mass media offer access to vast audiences at a cost per person that is usually a fraction of what it costs to reach individuals through clinics, it also requires tightly controlled message content. It is much easier to monitor a message for accuracy in a mass media campaign than among every provider and counselor. (AIDSCAP)

Many experts in the social marketing field emphasize that condom campaigns can reach large numbers of people, particularly men. These campaigns can also promote condoms for both disease and pregnancy prevention. With such a double message, a woman can bring up pregnancy prevention as a reason for using condoms. This may reduce the chances that her husband will think she is unfaithful.

To complement mass media efforts, individual counseling can increase condom use. Illustrated brochures on correct condom use, wooden penis models for demonstrating proper condom use and other counseling approaches also contribute to increased condom acceptability.

Experts believe that changing sexual behavior, as with other personal matters, such as changing a diet, requires moving through several stages. First, a person considers making the behavior change, then may decide to use the new behavior on a sporadic basis, and finally may continue the change over time. Thus, different strategies for increasing acceptability of condoms may be more

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successful if applied to people at different points in these stages of behavior change.

To sustain a change in sexual behavior requires more than information, say experts. People must be encouraged to assess the stage of behavior change they are in and move toward the maintenance stage. To do this, counseling needs to help people ask themselves such questions as: What is important in my life? and What behaviors do I want to use for my life? For example, one study identified which groups of women need more intensive counseling for consistent condom use. It found that people who choose condoms as a contraceptive method require more counseling than people who use condoms as a backup method. This is because those choosing it as their primary method may have underestimated how hard it is to use condoms every time. (Oakley)

Few studies have examined what types of counseling result in sustained behavior change. Counseling does appear to increase condom use when done with both partners in a monogamous situation and when focused on skill building. For example, in a project that counseled heterosexual HIV serodiscordant couples every six months over six years, there were no HIV seroconversions. Also, condom use and abstinence increased. (Padian) Another study compared women who received several 90-minute group counseling sessions and a one-month follow-up session in skill training about condom use to women who received a general health message. Three months later, condom use had more than doubled among the first group, but had only increased marginally among those receiving the general message. (Kelly)

Political and policy decisions can also affect condom acceptability. In Thailand, a nationwide "100 percent condom" program at commercial sex establishments, requiring that sex workers always use a condom, has resulted in a sharp decrease in STD rates. Local police linked STD infections to specific brothels as a means of enforcing the policy. Condom use at

commercial sex establishments has increased from about 14 percent when the program began in 1989 to 90 percent in 1994. (Rojanapithayakorn; KE Nelson)

Product Choices

Among reasons cited for not using condoms, several are related to product attributes, including fear of breakage, inconvenience, interruption and awkwardness of foreplay, loss of sensation, inability to maintain an erection, discomfort, and allergic reaction to latex. Condom manufacturers continue to refine the product so as to increase condom acceptability and market share (see page 18). Research on what product attributes condom users prefer should influence the type of products made available and development of new products.

Lubricants. The limited research on lubrication and acceptability suggests that users prefer pre-lubricated to non-lubricated condoms and, if adding a lubricant, prefer it to be water-based. (Regarding lubricants and condom failure, see Chapter 3.) In a prospective study designed to evaluate the impact of additional lubricant use on condom acceptability and failure, 268 U.S. couples were given equal numbers of condoms to be used with additional water-based lubricant, additional oil-based lubricant and no additional lubricant. A total of 3,216 latex condoms pre-lubricated with silicone were used in the study. Based on a five point scale ranging from "liked very much" to "strongly disliked," participants indicated a significant preference for water-based lubricant as compared to oil-based or no additional lubricant ($p < 0.001$). (Steiner)

In another study, current condom users in Bangladesh, Egypt, Ghana, Honduras and Mali were recruited through family planning clinics, pharmacies and community distribution programs; more than 90 percent were using pre-lubricated condoms. A total of 633 men were provided with more than 5,000 spermicidally-lubricated condoms and returned for a one month follow-up interview. The men

rated the study condoms very positively for several measures of acceptability, both in general and in comparison to the condoms they usually used. For example, if given a choice for future use, more than three fourths of the men reported they would choose the study condoms. The authors cautioned, however, that the results may have been biased in favor of the study condoms due to participants' desire to please the interviewers or due to the novelty of the spermicidally-lubricated product. Complaints most often reported about the study condoms included too much lubrication and brief discomfort. (Potter)

The U.S. magazine *Consumer Reports* provided information about condom preferences, based on a 1989 questionnaire sent to 3,300 of its readers, with about half responding. Approximately three of every four respondents preferred lubricated over non-lubricated condoms. In another U.S. study (Grady), about half of the current condom users who responded to a national survey of 3,000 people indicated that the right amount of lubrication is an important characteristic when choosing a condom.

Pre-lubricated condoms or the use of additional lubricants may be less acceptable among those in countries where some couples practice "dry" sex. In those cultures, some women engage in a variety of practices in order to dry out the vagina to increase sexual pleasure, as discussed further in Chapter 3. (Runganga; Brown)

Width of Condom. FHI has conducted a series of human use studies in developing countries to evaluate the acceptability of pre-lubricated latex condoms of different diameters. The size of these condoms is measured in terms of their lay-flat widths (the width of a flattened condom measured perpendicular to the length). Studies were conducted in Asian countries using smaller condoms and in African countries using larger condoms, assuming that penis size might affect acceptability of different sized condoms (see Chapter 3 for discussion of penis size).

Convenience samples of about 150 men in three Asian countries (Philippines, Sri Lanka and Nepal) compared smaller condoms (49 mm lay-flat width) with standard condoms (52 mm). More than 2,000 condoms of each width were used. Findings from all three sites suggest approximately equal proportions of men prefer each of the two condom sizes. (Andrada; Neupane) When men from the site in the Philippines rated the two condoms on a five point scale from "liked very well" to "strongly disliked," the distributions of ratings were almost identical. About equal proportions of men liked the smaller or the standard width condoms with respect to which condom stayed on better, which was more comfortable to wear, and which they would prefer for future use. Findings were similar in Sri Lanka, except that almost two-thirds of the participants preferred standard condoms for future use.

In Nepal, results were mixed: about two-thirds of the men indicated that they liked the standard condoms better, while a similar proportion reported that the smaller condoms were "more comfortable." More than half of the participants indicated no preference with respect to future use and about a third preferred the smaller condoms.

Studies in Ghana, Kenya and Mali compared larger condoms (55 mm lay-flat width) with standard condoms (52 mm). Each of 272 men from all three countries tested one condom of each width. More than half the men chose the standard condom as the one they "liked better" and/or as the one they would use in the future, while almost equal proportions of men chose each of the two sizes as "more comfortable to wear." In Mali, however, about two-thirds indicated a preference for the larger condoms for at least one of each of the three measures of acceptability above. (Joanis)

Given the acceptability parameters included in these studies, there was no clear indication that, based purely on user preferences, people would choose a condom width that is not currently widely available to them

The limited research on lubrication and acceptability suggests that users prefer pre-lubricated to non-lubricated condoms.

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Acceptability and Product Development

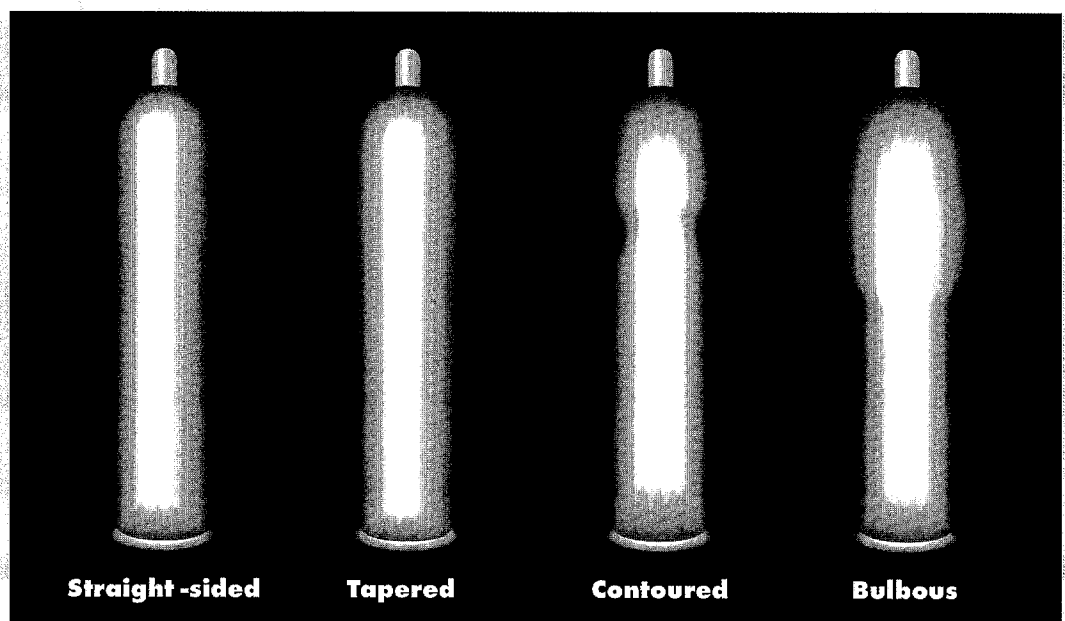
by **Caroline E. Gilmore**

Increased acceptability of condoms means more sales for condom manufacturers. Hence, condom producers have an interest in exploring product designs that can increase acceptability. These include new approaches to lubricants, dimensions, shape/design and packaging. Also, condom developers, including those developing synthetic (non-latex) products, can explore designs that are thinner, stronger, less likely to slip, easier to put on, and with more variety in color, texture, scent and flavor. Any change or modification in a condom property, however, should be carefully evaluated for its effect on condom failure so that efficacy is not sacrificed for increased acceptability.

Lubricants. Manufacturers currently pre-lubricate most condoms, using water-based, silicone-based or other lubricants. Lubricants

enhance consumer acceptability by making condoms easier and more comfortable to use. Pre-lubricated condoms may also decrease breakage and contribute to correct usage. Insufficient lubricant may lead condom users to add their own lubricant. However, appropriate lubricants may not be readily available, so pre-lubricated condoms may result in more correct condom usage in some areas. Silicone lubricants have also been found to help prevent deterioration under adverse storage conditions. (Free)

By adding spermicides to pre-lubricated condoms, manufacturers are able to suggest on package labeling and elsewhere that these condoms may provide extra protection from STD transmission. This is a successful marketing tool, with about one third of the pre-lubricated condoms in the U.S. now containing spermicides. While spermicides do kill sperm and STD organisms, including HIV, in the laboratory, research among actual users indicates that adding spermicide to condoms



does not increase their effectiveness against STDs. (Roddy)

Including nonoxynol-9 (N-9) or another spermicide on pre-lubricated condoms results in a more expensive product with a shorter shelf life. Spermicides have a designated shelf life of two to three years. In contrast, condoms lubricated without spermicides usually have a five-year shelf life. Also, little research has examined how N-9 or other spermicides interact with chemical components of the latex formulation, which could affect the condom's integrity.

Dimensions. Future research could evaluate various thicknesses and thickness profile approaches, such as making condoms thicker at the tip. Most experts think that the closed end of the condom is subjected to the most stress during intercourse. Making a condom that is thicker at the closed end and thinner at the open end might result in decreased condom breakage and increased acceptability.

Traditionally, manufacturers have faced the dilemma of trading thickness for sensitivity; that is, the thinner condom allows more sensitivity, but the thicker condom is less likely to break. The use of synthetic materials may permit having strong condoms that are also very sensitive.

Shape/Design. Manufacturers are exploring changes to the traditional straight-sided or

contoured condom shape. Several condoms marketed in the U.S. are bulbous at the closed end and similar in width to a straight-sided condom at the open end. This looser fit provides the penis with more room to move, supposedly allowing friction comparable to having intercourse without a condom. The bulbous shape may also be more comfortable and provide greater sensitivity than tighter-fitting condoms. One experimental synthetic design, the Ezon condom, is a baggy sheath that is slipped on like a sock rather than rolled on (see Chapter 7).

Packaging. Manufacturers say that users often complain about packaging. Packages are difficult to open, especially some of the stronger foil packages. However, foil packages help preserve condom quality during storage. Developing a foil package that is easy to open without having to use a sharp object not only would increase acceptability but also would reduce the likelihood of breakage.

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over a standard condom. The impact of condom width on breakage and slippage is reviewed in Chapter 3.

Thickness. FHI has also carried out studies to evaluate acceptability of thicker condoms. Theoretically, these would be stronger, but they also could allow less sensation. Sixty-five current condom users per country were recruited in Mali, Sri Lanka and the Dominican Republic. At the time of the studies, most men were using pre-lubricated latex condoms

with a standard thickness of .066 mm, compared to the condom being tested of .086 mm. (Cordero 1990)

Participants were not told that the study condoms were thicker, but they were told that these condoms were stronger. Thus, although the results suggest a fairly consistent preference for the "stronger" condom, they should be interpreted with some caution.

In all three sites, about two-thirds of the men chose the stronger condom with respect

...the combination of
innovative condom
shapes and thickness
may lead to more
acceptable condoms.

to their "general preference." At least three-fourths of the men in each site reported that they would "prefer to purchase" the stronger condom for future use. Slightly more men also preferred the stronger condom based on "comfort" and "sensation."

In contrast, the *Consumer Reports* study found that more than a third of the respondents preferred extra-thin condoms. Consistent with these findings, more than two out of five condom users included in the U.S. national survey reported that they prefer thinner condoms. (Grady)

Data evaluating the role of thickness in condom acceptability are insufficient to suggest a clear relationship. As discussed below, the combination of innovative condom shapes and thickness may lead to more acceptable condoms.

Formulation. In a six-country evaluation of how well men liked condoms of two different latex formulations, FHI found that the formulation rarely affected acceptability. Made by the same manufacturer, the condoms were pre-lubricated latex of similar thickness (and therefore, theoretically of similar sensitivity) — one standard formulation, which was more elastic, and one so-called "extra-strong" formulation, which was less elastic. (For breakage results, see Chapter 4.) About 100 men were recruited in each of six sites (Dominican Republic, Jamaica, Kenya, Mali, Mexico and Sri Lanka) to use five of each type of condom. Neither participants nor interviewers were told what type of condoms were used in the study.

In Jamaica, Sri Lanka and Kenya, slightly more men favored the standard formulation in terms of which they "liked better," which were "easier to put on," and/or which were "more comfortable." In Jamaica, there was not a strong preference with respect to future use. (Figueroa) In Sri Lanka and Kenya, however, about two-thirds preferred the standard condom for future use. (Abeywickrema; Ndumbu) In both Mexico and the Dominican Republic, men gave the two condoms very

similar ratings. (Alvarado; Cordero 1991) Only in Mali did the men find the stronger condoms to be more acceptable. (Sidibe) More than two-thirds liked the stronger condoms better and/or found them more comfortable. Just over half of the Malian men also indicated that the "extra-strong" condoms would be their choice for future use.

Shape/Texture. Some research suggests that the shape and fit of a condom might affect acceptability. In a prospective study, participants compared a standard latex condom with an experimental latex condom that fit loosely over the tip of the penis. This condom design is intended to facilitate friction during intercourse between the inside of the condom and the most sensitive area of the penis (the glans), functioning like a vaginal liner rather than a condom sheath. The study findings suggest that despite being thicker, the experimental condom was at least as pleasurable and comfortable as the standard condom. (Trussell 1992a)

Other human trials of loose fitting non-latex condoms suggest that this type of design modification may lead to enhanced sensitivity and acceptability. (Bernstein) About 40 percent of the respondents in the U.S. national survey identified a condom reservoir tip as a preferable feature in a condom. (Grady) More research is needed to determine if other variations in condom shape could lead to improved acceptability.

Only limited data exist on textured or ribbed condoms. About 25 percent of the *Consumer Reports* respondents indicated that they preferred textured condoms, while a similar proportion responded that they would not use them. Except for condom color, ribbing was the least frequently mentioned characteristic looked for by condom users in the U.S. survey. (Grady)

Materials. Limited published research has compared acceptability of latex to synthetic condoms. A randomized, controlled efficacy study with 800 couples and more than 3,500 condoms compared standard latex and

polyurethane condoms (both packaged with a silicone-based lubricant). Differences in participant complaints (e.g. irritation, itching) about the two types of condoms were minimal. Male participants did report more frequent penile constriction with use of the latex than the polyurethane condom. The participants found the two condoms similar in terms of recommending or choosing for future use, lubrication, fit, appearance, sensitivity and odor. They rated the latex condom as easier to put on than the polyurethane condom. (A Nelson 1997)

In a similar study among 360 couples who used more than 2,000 condoms, the polyurethane condom was slightly thinner than in the study described above. Participants reported more difficulty unrolling the polyurethane condom and more problems with penile constriction with the latex condoms. Both men and women perceived that the polyurethane condom broke and stretched out of shape more often, and the latex condom allowed less stimulation. Polyurethane condoms received better ratings for sensitivity, odor and overall lubricant preference, while latex condoms were given higher ratings for fit and dependability. (A Nelson 1996)

In a study among 49 couples who tested 478 latex and non-latex condoms, participant responses to several indicators of acceptability suggest that the two types of condoms were similar in terms of acceptability. (Trussell 1992b) Ratings for fit, appearance, overall sensitivity or pleasure experienced were generally in the same direction as those discussed above, but they were not significantly different for the two condoms.

These studies suggest that synthetic condoms have some distinct advantages and disadvantages, and can achieve at least equal footing with latex condoms in terms of acceptability.

Some respondents to the *Consumer Reports* questionnaire preferred natural skin condoms while others did not. Regardless of acceptability, skin condoms (made from lamb

cecum, part of the intestine) provide less protection against STDs and hence are not a good choice for those needing disease protection. For more information on both synthetic and skin condoms, see Chapter 7.

Conclusion

Improving the acceptability of condoms is a multi-faceted process. Surveys indicate many reasons why people do not use condoms, ranging from diminished sexual pleasure to fear of a partner's reaction. In the AIDS era, many types of efforts are being used to change sexual behaviors, with increased condom use a primary strategy for reducing the spread of all STDs. Increasing condom use will require more government and cultural approval, increased availability of condoms, more information, increased skill on negotiating condom use, more promotion, and better and more focused counseling.

Changes in product attributes do not appear to play an important role at this point in getting people to use condoms initially. However, changes might make people more willing to keep using condoms once they start. Limited research suggests that use of additional lubricants could increase acceptability among some groups. With some exceptions, variations in width, thickness and latex formulation generally appear to have limited impact on acceptability. Changes in shape appear to offer some promise for increased acceptance of condom use among certain groups. Limited research comparing latex to synthetic condoms suggests comparable acceptability with potential for future advances.



Basketball goal advertises Trust brand condoms to increase acceptability.

Richard Lord

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User Behaviors and Characteristics Related to Condom Failure

by Alan B. Spruyt

Most condom failure occurs as a result of the behaviors of the user, not due to a faulty device. Some user characteristics are also related to condom failure. Hence, understanding which behaviors and characteristics are most strongly associated with condom failure is critical to improving the effectiveness of condoms through public health messages and counseling.

Condom failure (breakage or complete slippage) is often concentrated among certain groups of people, rather than being distributed evenly among all users. What distinguishes this minority of condom users who are at increased risk of condom failure? What are the important background characteristics that are useful for identifying these condom users? What are their specific behaviors that lead to condom failure?

Among men who have used condoms in the past, those who have experienced condom failure are about twice as likely to have a condom failure in the future, compared to men without a past failure. Lack of experience with condoms and several other characteristics may also be associated with condom failure.

Research is less clear about which behaviors lead to condom failure. Behaviors that may be related to failure include opening condom packages with sharp objects, unrolling condoms before putting them on, using oil-based lubricants, having lengthy or intense intercourse, and practicing anal intercourse or vaginal drying.

Better knowledge of characteristics and behaviors that lead to failure may be useful for

screening or targeting condom users for counseling, education or other interventions. More understanding of these issues could also improve overall information, education and communication efforts about condoms, as well as help in the development of new types of condoms.

This chapter discusses research regarding condom failure in terms of:

- unequal distribution of condom failure among users
- user characteristics associated with condom failure
- user behaviors associated with condom failure, and
- issues for future research relating to user characteristics and behaviors.

Unequal Distribution of Failure

For most condom users, condom failure is rare. Several published studies that have evaluated the distribution of condom failures among participants suggest that a minority of condom users experience a disproportionate amount of failure. One published study and two reports, however, found more evenly distributed condom failure (see Table 3-1).

The most scientific analysis of uneven distribution patterns involved a prospective study of 177 couples who used 11 condoms each (1,947 total). The study compared the actual distribution of condom failure with a hypothetical distribution assuming condom

failure is random and not related to the couple (calculated using a binomial probability distribution). Sixty-two percent of the couples experienced no failure, almost twice as many as the 37 percent predicted to have no failure by the hypothetical model. In actual use, 29 percent had one to three failures, compared to 62 percent in the hypothetical; 9 percent experienced four or more failures compared to 1 percent in the model. The distributions in actual use and in the hypothetical model were significantly different, showing that condom failure among this cohort was associated with particular couples ($p < 0.001$). (Steiner 1993)

This study found that a small minority of users, 9 percent, were responsible for half of all failures. Other studies have shown similar patterns. The retrospective arm of a study among 44 female sex workers from Nevada, USA, gathered data on more than 41,000 condoms used prior to the interview. One woman reported 41 percent of all condom breaks, and three women reported nearly half of all slippage. (Albert 1995) During a study among 540 male and female family planning clients who used more than 3,700 condoms, 3 percent of the participants were responsible for 34 percent of the breaks. (Sparrow) Similarly, among 87 male STD clients who used more than 50 condoms in the previous year, four men experienced 30 percent of the total breakage. (Richters 1993) Distribution of condom failure was uneven, but less pronounced, in two evaluations comparing polyurethane with latex condoms (Nelson 1997, 1996)

In general, these findings suggest that specific characteristics and user behaviors of a minority of users lead to condom failure. Because condom failure is not equally distributed among all users, most condom users are likely to experience condom failure less often than the average failure rates reported in published studies imply. Moreover, published condom failure rates may vary across studies in part because of the differences in character-

Table 3-1. Selected Studies of Distribution of Condom Failure among Study Participants

Author	Sample; Design (Site)	Findings
Albert 1995	44 female CSWs, 41,127 condoms; retrospective arm (USA)	One woman (2%) reported 41% of all breakage; three women (7%) reported 47% of all slippage.
Sparrow 1994	540 men and women, 3,754 condoms; prospective (New Zealand)	16 participants (3%) were responsible for 34% of all breakage.
Steiner 1993	177 couples, 1,947 condoms; prospective (USA)	Almost twice as many couples reported no failure, and almost 10 times as many reported ≥ 4 condoms failed, as would be expected if failure were random.
Richters 1993	402 male STD clients, 13,691 condoms; retrospective arm (Australia)	Among the 87 men who reported using ≥ 50 condoms in the past year, 4 men (5%) experienced 30% of the breakage.
Nelson 1997	805 couples, 3,686 condoms (latex and polyurethane); prospective (USA)	76% of couples who reported polyurethane condom failure experienced only 1 failure. 90% of couples who reported latex condom failure experienced only 1 failure.
Nelson 1996	360 couples, 2,026 condoms (latex and polyurethane); prospective (USA)	76 % of couples who reported polyurethane condom breakage experienced only 1 break. 90% of couples who reported latex condom breakage experienced only 1 break.
Trussel 1992a	70 couples, 405 condoms; prospective (USA)	No couple experienced more than one condom break during intercourse or withdrawal.

istics and behaviors among different groups of study participants.

User Characteristics Associated with Condom Failure

A review of studies on condom use and characteristics of users indicates that a history of condom failure and less experience using condoms are risk factors for future failure. Other characteristics that may be associated with condom failure are young age, less education, less income, and large or circumcised penis (see Table 3-2).

Table 3-2. Selected Studies of User Characteristics Associated with Condom Failure

Author	Sample; Design (Site)	History of Failure	Less Experience w/Use	Younger Age	Less Education	Less Income	Larger Penis	Circumcised Penis
Spruyt 1998	386 men, 1,810 condoms; prospective (Mexico, Philippines, Dominican Republic)	F	F	F	F			
Nelson 1997	805 couples, 3,686 condoms (latex and polyurethane); prospective (USA)	F	F	B	F	B,S	B,S	F
Rugpao 1997	68 female CSWs, 5,040 sex acts; prospective (Thailand)			B				
Linberg 1997	1, 676 men (aged 17-22); retrospective national survey (USA)		B			B		
Nelson 1996	360 couples, 2,026 condoms (latex and polyurethane); prospective (USA)	B	B	B	B	B	B	B
Albert 1995	41 female CSWs, 353 sex acts; prospective arm (USA)	S	S					
Richters 1995	108 male STD and general practice clients, 4,809 condoms; retrospective (Australia)		F	S				S
Sparrow 1994	540 men and women, 3,754 condoms; prospective (New Zealand)	F	F					
Grady 1994	1,226 men (aged 20-39); retrospective national survey (USA)		F	F	F	F		
Steiner 1993	177 couples, 1,947 condoms; prospective (USA)	F	F	F	F			
Trussell 1992a	70 couples, 405 condoms; prospective (USA)	B	B					
Trussell 1992b	49 couples, 241 Tactylon and 327 Trojan-Enz condoms; prospective (USA)	F	F					
Chan-Chee 1991	191 men, 63 women, 8,230 condoms; retrospective (France)		B					
Hatcher 1988	195 women, 26,294 condoms; retrospective (USA)		B					

B Breakage studied, association found

B Breakage studied, no association found

S Slippage studied, association found

S Slippage studied, no association found

S Slippage studied, lower slippage rate found

F Failure (breakage and/or slippage) studied, association found

F Failure studied, no association found

A recent prospective study was designed specifically to test the hypothesis that past failure is predictive of future failure. It involved 386 men and 1,810 condoms. The men who reported condom failure during the year prior to the study reported approximately twice as many condom failures during the study as those who had also used condoms but did not experience failure during the year prior to the study ($p \leq 0.03$, depending on site). (Spruyt)

Other studies have found similar results, as indicated in the first column of Table 3-2. Two prospective trials (805 couples and 3,686 condoms in larger of the two) involving polyurethane and latex condoms found that history of condom breakage was significantly associated with polyurethane condom failure during the study (odds ratio ≥ 2.1 , $p \leq 0.01$). (Nelson 1997, 1996) In general, one should note that factors related to failure of polyurethane and latex condoms may not be the same, because of differences in product attributes (see Chapter 7).

In a subset of 143 couples who used 1,573 condoms during a prospective study, reported condom failure was more than twice as high among couples who had experienced condom breakage in the year prior to the study, compared to those who had also used condoms, but had not experienced breakage ($p = 0.0001$). (Steiner 1993) A multi-site prospective study of 540 family planning clients (3,754 condoms) found that a history of breakage during the three months prior to the study was significantly related to breakage and slippage during the study ($p < .001$). (Sparrow) A prospective study among 41 sex workers involving 353 acts of vaginal intercourse found that condom slippage during withdrawal was related to slippage prior to the study. (Albert 1995) Although two studies did not find statistically significant associations with past failure, these results may have been a consequence of few cases of failure or relatively small study samples. (Trussell 1992a, 1992b)

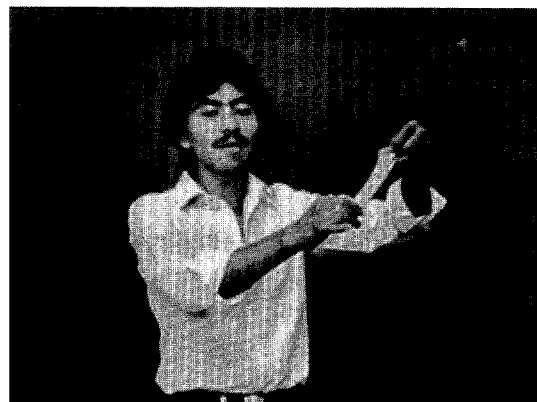
Findings from several studies among diverse populations and sites suggest that less

experience using condoms is associated with condom failure. In the two large polyurethane studies described above, two measures of condom inexperience (couple and lifetime) were related to breakage and/or slippage. (Nelson 1997, 1996) The prospective study among 540 family planning clients described above found that experienced couples (both partners had used condoms for more than five years) reported significantly less breakage during the study than couples with less condom experience ($p \leq 0.003$). (Sparrow)

Similarly, in the prospective study among 177 couples outlined above, couples who did not use a condom in the year prior to the study were twice as likely to experience condom failure during the study, compared to those who had used at least one condom during the year prior to the study ($p < 0.001$). (Steiner 1993)

Results of retrospective studies conducted in different countries, among diverse groups of men and women (e.g. of various sexual orientations, ages, occupations), also suggest that less experience with condom use is related to condom failure. (Richters 1995; Linberg; Grady; Chan-Chee; Hatcher) Although other factors may contribute, some researchers attribute exceptionally low failure rates among sex workers to the considerable experience the sex workers have using condoms. (Albert 1995; Chan-Chee; Richters 1988) In contrast to such results, two studies did not find an association between level of experience and condom failure. (Spruyt; Trussell 1992b)

Research has also evaluated age, education and income for potential relationships with condom failure. Results from the two evaluations of polyurethane condoms suggest that



Outreach worker discusses condom use.

Richard Lord

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Table 3-3. Selected Studies of User Behaviors Associated with Condom Failure

Author	Sample; Design (Site)										
		Open with Sharp Object	Unroll Before Donning	Difficulty in Donning	Lengthy Sex	Intense/Rough Sex	Oil Base Lubricant	Water Base Lubricant	Lubricant Unspecified	Vaginal Drying	Anal Sex Position During Sex
Spruyt 1998	386 men, 1,810 condoms; prospective (Mexico, Philippines, Dominican Republic)	B	F		S	S					
Nelson 1997	805 couples, 3,686 condoms (latex and polyurethane); prospective (USA)			B	F			F			F
Rugpao 1997	68 female CSWs, 5,040 sex acts; prospective (Thailand)				B	B		B			
Linberg 1997	1,676 men (aged 17-22); retrospective national survey (USA)									B	
Van de Wijgert 1997	149 female CSWs; prospective (Zimbabwe)								B		
Nelson 1996	360 couples, 2,026 condoms (latex and polyurethane); prospective (USA)			B	B			B			B
Gabbay 1996	438 patients, 481 controls (male and female students); retrospective (UK)							F			
Richters 1995	108 male STD and general practice clients, 4,809 condoms; retrospective (Australia)		F		F			S		B, S	
Steiner 1994	268 couples, 3,216 condoms; prospective (USA)					S	B				
Sparrow 1994	540 men and women, 3,754 condoms; prospective (New Zealand)						B*	F			F
Grady 1994	1,226 men; retrospective national survey (USA)									S	
Trussell 1992a	70 couples, 405 condoms; prospective (USA)					S					
Trussell 1992b	49 couples, 241 Tactylon and 327 Trojan-Enz condoms; prospective (USA)							F			
Chan-Chee 1991	191 men, 63 women, 8,230 condoms; retrospective (France)							B		B	

B Breakage studied, association found

B Breakage studied, no association found

B Breakage studied, lower breakage rate found

B* Saliva was the lubricant studied

S Slippage studied, association found

S Slippage studied, no association found

F Failure (breakage and/or slippage) studied, association found

F Failure studied, no association found

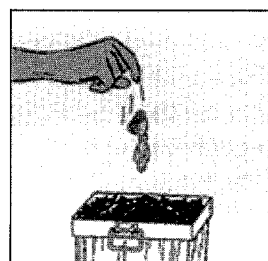
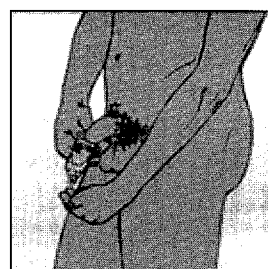
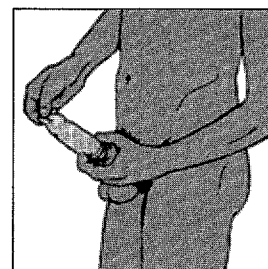
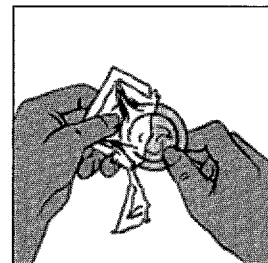
F Failure studied, lower failure rate found

Using a Condom Correctly

by Alan B. Spruyt

Learning to use condoms correctly is not difficult but does involve some specific steps. The checklist below describes the steps a user should take to use the condom with maximum effectiveness.

- Check the condom package to be sure that it is not torn or damaged.
- Check the expiration or manufacturers' date on the package to be sure it is not expired (latex condoms > 5 year old, or > 3 years old if packaged in N-9 should not be used). Do not use a condom that is brittle, dry or has changed color (darkened).
- Open the package carefully with fingers to avoid tearing the condom. Do not use sharp objects such as scissors, teeth or knives.
- To prevent the exchange of sperm or microorganisms between sex partners, there should be no genital contact before a condom is put on.
- Unroll the condom directly onto the erect penis. Be sure to unroll it all the way to the base of the penis.
- Many condoms have a receptacle on the end for semen. If the condom does not have one, some recommend holding the end of the condom while unrolling it onto the penis to create a space for the semen; however, research is needed on what impact this practice has on condom breakage or slippage.
- Starting to unroll the condom wrong side out on the penis and then flipping it over to put it on correctly may contaminate the outside of the condom with pre-ejaculatory fluid containing STD microorganisms. If this happens and it is suspected that contamination has occurred, the condom should be thrown away and replaced with a new one.
- Use only water-based lubricants such as K-Y jelly, spermicidal gels or creams. Oil-based products such as petroleum jelly, hand lotion, or mineral or vegetable oils should never be used because they can weaken latex, making the condom more likely to break. More data are needed to determine if saliva is an appropriate lubricant.
- After ejaculation, withdraw the penis from the vagina while the penis is still erect.
- Hold on to the rim of the condom while removing the penis to help prevent the condom from slipping off and the semen spilling into the vagina.
- After the condom is removed, genital contact should be avoided to prevent transfer of residual sperm or STD microorganisms on the glans or in the urethra.
- To dispose of a condom properly, put it in a trash container or bury it. Condoms should not be flushed down a toilet.
- Use a new condom for each act of intercourse. A condom should never be washed and reused as this can substantially weaken the latex.



Continued from page 27

being 25 years old or younger may be related to condom breakage (Nelson 1997, 1996) A study among commercial sex workers found that breakage was less likely among clients who were more than 30 years old. (Rugpao) Another study including men from health clinics found higher slippage rates among young men. (Richters 1995) At least three studies did not find this association, however. (Spruyt; Grady; Steiner 1993)

Some research also suggests that less education (measured in years of formal schooling) is related to condom failure. (Steiner 1993; Spruyt) Although participants with less education reported more condom failure in both of the polyurethane condom trials and in a U.S. national survey of men, there were not statistically significant differences in these rates (Nelson 1997, 1996; Grady). At least four studies in the U.S. (two prospective, two retrospective) have evaluated the relationship between income and condom failure. All four suggest less income is a risk factor for breakage and/or slippage. (Nelson 1997, 1996; Linberg; Grady)

Among U.S. studies reviewed here, four have evaluated the relationship between ethnicity/race and condom failure. Although these findings are relevant to the U.S., they may have little application to other regions and cultures. Two of these studies suggest that male ethnic/racial minorities are more likely to experience condom failure (Nelson 1997; Grady). Two others reported higher failure rates among male minorities; however, the differences were not statistically significant. (Nelson 1996; Steiner 1993)

Research has begun to evaluate important anatomical and physiological causes that may contribute to condom failure, such as penis size and circumcision status. Closely related to penis size, research has also examined condom failure in terms of different condom widths.

Participants in the two large polyurethane condom trials were asked to measure the circumference and length of their penises while erect. Based on results on polyurethane

condoms only, both studies found that larger penis circumference is a risk factor for breakage, and one found that larger circumference is protective against slippage. (Nelson 1997, 1996) One of the studies also suggests that longer penis length is associated with breakage. (Nelson 1996)

The World Health Organization bases its specifications for condom width on consumer preference and penis size, citing three studies. Taken together, the studies show significant variations in penis size within all population groups, but also indicate that men of African descent on average have a slightly wider and longer penis size, Caucasian men have a medium size, and Asian men a slightly narrower and shorter size. (WHO)

Based on the consideration that anatomical differences exist among regions, a series of FHI studies were conducted in three Asian countries to compare small and standard width condoms (49 mm and 52 mm), and in three African countries to compare larger and standard width condoms (55 mm and 52 mm). Among the African sites, breakage rates were slightly higher and slippage was slightly lower for the smaller of the two condoms being compared. (Joanis) However, results from the Asian sites were inconsistent. (Neupane; Andrada) Moreover, almost none of the differences in breakage and slippage rates from either the Asian or African sites were statistically significant. Thus, results from these studies pertaining to penis size and condom failure were inconclusive.

A retrospective study in Britain, where most condoms are 52 mm in width, suggests penis size could affect condom failure. Participants classified themselves as either white, black or Asian. Eighteen percent of blacks, 7 percent of whites and no Asians reported frequent breakage. In contrast, 21 percent of Asians, 8 percent of blacks and 2 percent of whites reported frequent complete slippage. (Tovey)

Data regarding circumcised men and condom failure are limited and inconclusive.

**Research has
begun to evaluate
important anatomical and physiological
causes that may
contribute to condom
failure, such as penis
size and circumcision
status.**

Findings of one retrospective study suggest men with a circumcised penis are more likely to experience condom slippage. (Richters 1995) However, neither of the large polyurethane condom trials found a relationship between circumcision status and condom failure. (Nelson 1997, 1996)

User Behaviors and Condom Failure

Prospective studies and anecdotal evidence suggest that several behaviors may be associated with condom failure, including: opening condom packages with sharp objects, unrolling the condom before donning, lengthy or vigorous sex, using excessive lubrication (especially oil-based lubricants), reducing natural vaginal lubrication, anal or oral intercourse, having intercourse in specific positions, and re-use of condoms (see Table 3-3).

A study in Mexico, the Philippines and the Dominican Republic (386 men, 1,810 condoms) was designed in part to evaluate behaviors that may lead to condom failure. Condom breakage was associated with opening condom packages with sharp objects (teeth, scissors, knives or pencils), and both breakage and slippage were associated with unrolling condoms before donning. (Spruyt) Findings from the two large polyurethane condom trials were mixed: difficulty donning condoms was associated with breakage in one study but not in the other. (Nelson 1997, 1996) Another study conducted among male STD and general practice clients provides evidence that pulling condoms on with fingers on the inside may reduce the risk of failure. (Richters 1995)

In the multi-country study described above, slippage was also related to lengthy or intense intercourse. (Spruyt) Similarly, a prospective study among sex workers found breakage was related to lengthy or intense intercourse. However, the studies of polyurethane condoms and the study among male clients do not suggest duration of intercourse is related to failure. (Nelson 1997, 1996; Richters 1995)

A common instruction for proper condom use is to pull out when the penis is still erect and to hold the condom when pulling out (see related article page 29). However, in the multi-country study, more than half of the withdrawals took place after loss of erection, and 44 percent of the condoms were not held during withdrawal. Despite such high rates, these behaviors did not appear to be associated with condom slippage in the bivariate analysis. (Spruyt) Sizable proportions of participants in other studies of the general population have also reported these two behaviors. (Oakley)

Another common instruction for condom use is not to use oil-based lubricants. This is based on laboratory research that suggests that latex can deteriorate rapidly when oil-based lubricants are added, making them more likely to break, (Voeller) and on anecdotal evidence of breakage and slippage when using such oil-based lubricants as petroleum jelly, hand lotion, or mineral or vegetable oils.

In two studies that have evaluated the impact of adding oil-based lubricants, both have found an association with slippage. A prospective study, using new and aged condoms pre-lubricated with silicone, compared breakage and slippage rates with no additional lubricant, adding oil-based lubricants, and adding water-based lubricants. Adding an oil-based lubricant resulted in higher slippage rates, which were statistically significant ($p=0.004$). Adding oil-based lubricants also resulted in the highest breakage rates for both new and aged condoms, but the differences were not statistically significant when compared to using no lubricant or a water-based lubricant. (Steiner 1994) Findings of a study among 70 family planning clients also suggests that use of additional oil-based lubricants is related to slippage. (Trussell 1992a)

In the prospective study comparing various lubricants, water-based lubricants decreased breakage rates among old condoms and showed some increase in slippage rates

In two studies that have evaluated the impact of adding oil-based lubricants, both have found an association with slippage.

Continued on page 33

Defining "Condom Failure"

by Alan B. Spruyt

As used in this monograph, the term "condom failure" refers to breakage or complete slippage of the device, either of which can result in leakage of bodily fluids. Condom failure may or may not result in pregnancy or disease transmission. Condom failure refers only to what happens to the device, not to the consequences of the failure.

Condom breakage can be in the form of a burst, rip or tear, which may occur at the tip, along the shaft or near the opening of the condom. Breakage can occur while opening the condom package, putting the condom on the penis, during intercourse, withdrawing the penis, or removing the condom.

Slippage may be partial or complete. During partial slippage, part or all of the condom slips down the shaft of the penis. Partial slippage can also happen in the form of tip displacement, in which case the closed end of the condom is no longer held tightly around the end of the penis. For complete slippage to occur, the condom must become separated from the penis. Slippage can occur during intercourse or withdrawal.

Researchers have gathered data on condom failure during human use in a variety of different ways, making comparisons across studies difficult. To address this problem, standardized definitions of condom failure and minimum standards for data collection and presentation have been proposed. (Steiner) The proposed standard definitions of condom failure are summarized below.

■ **Nonclinical breakage rate** — number of condoms reported to have broken while opening the package or putting on the condom divided by the number opened.

■ **Clinical breakage rate** — number of condoms reported to have broken during intercourse or withdrawal divided by the number of condoms used during intercourse.

■ **Total breakage rate** — number of condoms reported to have broken (nonclinical and clinical) divided by the number of condoms opened.

■ **Complete slippage rate** — number of condoms reported to have slipped completely off the penis during intercourse or withdrawal divided by the number of condoms used during intercourse (if participants report a clinical break and a complete slip, only the clinical break is counted).

■ **Total clinical failure rate** — number of condoms reported to have broken during intercourse or withdrawal, or slipped off completely divided by the number used during intercourse.

■ **Total failure rate** — number of condoms that have broken (nonclinical and clinical) or slipped off completely divided by the number opened.

In addition to the types of failure outlined above, data on breakage during removal of the condom from the penis and partial slippage should be reported as well. Moreover, data collected on the location of breakage may be useful information for manufacturers to consider when designing new condoms.

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(although not statistically significant). The study concluded that the negative impact of water-based lubricants on condom slippage may be outweighed by the protective influence on breakage, especially with older condoms. (Steiner 1994)

Another study found that using water-based lubricants was significantly associated with lower condom breakage rates but not with increased condom slippage. (Gabbay) The study compared 434 women seeking post-coital contraception after recent condom failure with a control group of 393 women seeking other health services. Among the study group (all of whom reported recent failure), fewer than 2 percent reported that they had used additional water-based lubricants with their condom. Among the 133 controls who reported no history of condom failure, 14 percent reported using additional water-based lubricants; among the 270 controls reporting some condom failure, 4 percent reported using water-based lubricant. Use of water-based lubricants was associated with lower failure rates, comparing the study group both to controls with no history of failure (odds ratio=8.9) and to controls who had experienced failure (odds ratio=3.6). Moreover, the relationship between use of water-based lubricants and increased slippage rates was not significant (odds ratio=1.0).

In one study in which additional lubricants used were almost exclusively water-based and among several studies in which the lubricant type is unspecified, most findings suggest no association between lubricant use and condom failure. (Rugpao; Nelson 1997, 1996; Richters 1995; Sparrow; Trussell 1992b; Chan-Chee) Regarding saliva use as a lubricant, a study among 540 family planning clients found it to be associated with breakage ($p=0.015$). (Sparrow)

There is limited research concerning the impact of altering vaginal lubrication and size on condom breakage. Although the prevalence of this behavior is unknown, several vaginal preparation methods have been documented

in Zimbabwe, Zaire and other sub-Saharan African countries, as well as Saudi Arabia, Haiti and Costa Rica. (Van de Wijgert; Civic; Pitts; Brown RC; Brown JE; Runganga) Women have reported douching with various solutions; wiping with newspaper, tissue or cloth; and inserting leaves, powders, cotton, wool or tampons into the vagina before sex. The purpose is to make the vagina drier and tighter, in order to reduce vaginal secretions and enhance sexual pleasure for both partners. Results of prospective research among sex workers, in addition to findings of focus group interviews among health clinic attendees and providers, suggest that these types of practices are associated with condom breakage. (Van de Wijgert; Runganga)

Data from several studies suggest that condom use during anal intercourse is associated with condom failure. (Linberg; Richters 1995; Sparrow; Grady; Chan-Chee) One of these also found an association between oral sex and failure. (Sparrow) Findings are limited and inconsistent regarding the influence of sexual position and condom failure. (Nelson 1997, 1996)

Conclusion and Future Research

More research is needed concerning user characteristics and behaviors that may be associated with condom failure. Sufficient data should be collected to enable analysis of potential correlates of condom breakage and slippage (e.g. detailed data on each condom used, regardless of whether failure occurred). Future research will also benefit from increasing the probability of cases of condom failure in a study population by oversampling (to a greater extent than in previous research) of condom users who have experienced condom failure in the past.

Key research questions that need attention are:

- With respect to characteristics of condom users, are age, education level, penis size or other characteristics predictive of failure?

- Are behaviors that have not been studied, such as squeezing air out of the condom tip and individual condom storage practices, related to condom failure?
- What is the relative contribution of specific behaviors to breakage and slippage, and what is the relative prevalence of these behaviors? If a given behavior is likely to result in condom failure, but almost never occurs, it should have a minor impact on failure rates. If a behavior is only weakly associated with failure, but commonly occurs, efforts to curb the behavior may have a significant impact on overall condom failure.
- Are factors related to condom failure different for non-latex versus latex condoms?

Building on current knowledge of characteristics and behaviors associated with condom failure, targeted intervention studies to test the applicability of these findings on counseling strategies would be useful. Future human use trials could be designed to determine if condom failure can be reduced through identifying condom users at increased risk of condom failure and providing them with counseling to discourage behaviors associated with condom failure.

A history of condom failure and less experience using condoms are risk factors for future failure. This knowledge could be built into personal counseling, information brochures and mass media messages about condom use. Thus, persons with these characteristics could be alerted to their greater potential risk of condom failure. While research findings on other characteristics are not as clear, characteristics that may be associated with condom failure include young age, less education, less income, and large or circumcised penis.

Research is less clear about which behaviors lead to condom failure. Several behaviors that may be associated with condom failure —

opening a condom package with sharp objects, unrolling condoms before putting them on, using oil-based lubricants and re-using condoms — are addressed by instructions for correct condom use. Other behaviors that may be associated with condom failure include lengthy or vigorous sex, anal sex or vaginal drying.

It is important to remember that condom failure is often concentrated among a minority of condom users. Certain characteristics and behaviors have been shown to be related to condom failure. For most condom users, condom failure is rare.



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Recent Advances in the Research, Development and Manufacture of Latex Rubber Condoms

by **Caroline E. Gilmore**

The latex rubber condom produced today is more reliable than ever before, due primarily to improved quality management, but also to better formulations and packaging. It is also generally safer in terms of possible health problems, although some new concerns are arising regarding allergic or other toxic reactions to various components of latex condoms such as vulcanization accelerators, latex proteins, spermicides and finishing powders.

Latex Formulation

Latex condoms are made by mixing various chemicals with natural liquid latex, a process that affects the chemical and mechanical properties of the final product. Natural latex rubber deteriorates due to exposure to oxygen, ozone, heat, humidity, ultraviolet and visible light, mechanical fatigue or heavy metal contamination. Recent formulation improvements have focused on the chemical processes of oxidation and vulcanization and on the mechanical properties of stress and strain.

Oxidation is the deterioration of latex due to exposure to oxygen. To help prevent oxidation, most manufacturers now add antioxidants to the latex formulation, usually phenol compounds.

Vulcanization, a chemical curing process, increases the strength and resilience of rubber by forming sulfur-sulfur crosslinks between polymeric strands of the latex. Unvulcanized latex rubber is weak, loses its shape and can be sticky like chewing gum. Vulcanization enables elastomeric materials to return to their shape more easily after being stretched and reduces

the amount of change in shape. The degree of vulcanization is controlled by the quantity and type of vulcanizate and temperature. Vulcanizing agents can act too fast or not fast enough, too thoroughly or not completely enough. If chemical agents added to the formulation work too long, excessive vulcanization in the package occurs, which can make condoms brittle, stiff and less elastic when opened and used.

In recent years, manufacturers have improved the control of the vulcanization process, using chemical activators and accelerators in a more reliable process. This has resulted in minimal or no in-package vulcanization.

Changes in the formulation affect the mechanical properties of stress and strain. A force can be applied to compress or to stretch a material. With condoms, stress refers to the amount of force needed to extend the latex rubber a specified amount; stress is related to condom strength. Strain refers to how far latex rubber can be stretched and is related to elasticity. Both stress and strain contribute to the resistance of latex to breakage.

The relationship of stress and strain properties is called "modulus." Researchers working with condoms generally use the concept of "Young's modulus," which refers to a ratio of stress over strain (with stress as the numerator and strain as the denominator). Manufacturers, on the other hand, use the concept of "percent elongation modulus." This refers to the amount of stress per unit of cross-sectional area of the condom, measured in megapascals of pressure, at a given extent of

strain through elongation, usually at 300 percent or 500 percent.

In either case, the term modulus refers to the stiffness or hardness of a material: a low-modulus material is more pliable and elastic, such as rubber bands, and a high-modulus material is stiffer but able to withstand a greater force, such as steel. This monograph uses the concept of "Young's modulus," since the studies discussed here use that concept.

Since latex condoms need to be both elastic and strong, the combination of the mechanical properties determines how reliably a condom performs. Manufacturers appear to be moving toward producing a more elastic condom. Findings from a series of FHI studies at six international sites compared a higher-modulus condom, called "extra-strong," with a lower-modulus, more elastic condom in human use. More than 3,000 of each type of condom were used. The more elastic condom broke less frequently (3.3 percent), compared to the "extra-strong" condom (4.3 percent), although the difference was not statistically significant. (Abeywickrema; Alvarado; Cordero; Figueroa; Ndumbu; Sidibe)

The mechanical properties of latex rubber condoms can change during aging if the latex film is not well formulated and protected from oxidation. Findings from a study conducted by PATH, with support from the FDA and FHI, found that stress and strain properties of latex condoms appear to deteriorate for different reasons, some oxygen-dependent and some oxygen-independent. Stress properties appear to be very susceptible to deterioration due to oxidation, while strain properties appear to be more sensitive to deterioration due to excessive vulcanization. The study compared changes in condoms artificially aged in the laboratory to those stored for various lengths of time and under various conditions in the United States and in four other countries. (Free)

By evaluating the stress and strain properties of new and aged condoms from the same condom batch, laboratory tests can yield a

Table 4-1. Stress, Strain and Modulus

Term	Refers to	Indicator (Lab Test)
Stress	Pressure or force	Tensile breaking strength (tensile) Breaking force (tensile) Air burst pressure (air burst)
Strain	Elasticity or extensibility	Percent elongation (tensile) Air burst volume (air burst)
Young's Modulus*	Ratio of stress to strain (stress is numerator; strain is denominator)	Tests listed above for stress and strain
Percent Elongation Modulus*	The amount of force or pressure applied to a material to extend that material to a percentage of its original elongation	Tensile breaking strength (tensile) Percent elongation (tensile)

* Higher modulus means higher proportion of stress properties, yielding stiffer condoms. Lower modulus means higher proportion of strain properties, yielding more elastic condoms. Two condom formulations can have the same degree of stress properties, but have different strain properties (or vice-versa) and thus have different moduli.

"fingerprint," revealing one of three predominant causes of deterioration of the condom:

■ **Oxidative Deterioration** — A decrease in stress properties, with little or no decrease in strain properties, suggests oxygen-permeable or defective packaging (i.e., a hole in the package or an insufficiently sealed condom package) and a lack of antioxidant protection in the latex formulation.

■ **Shelf Vulcanization** — A decrease in strain properties, with little or no decrease in stress properties, suggests that the condoms were well protected from oxidative deterioration by good packaging but underwent shelf vulcanization, resulting in a stiffer, less elastic condom.

■ **Localized Deterioration** — A decrease in one indicator of stress properties (air burst pressure), with little or no decrease in the other two stress indicators (tensile strength and break force), suggests localized deterioration at the tip or parts of the condom unprotected by the condom roll. It also suggests high-temperature exposure and/or poor packaging. (Free)

Condom Packaging

Currently, most latex condoms are packaged in plastic cellophane, aluminum foil, or aluminum foil laminated with plastic cellophane. Some paper and paper laminates have been used worldwide, and may still be used in developing countries. The type of packaging affects the extent of condom deterioration during storage due to ultraviolet or visible light, oxygen, ozone, humidity, friction in the package and extreme temperatures.

Bill Richards/RTI



Various condom brands and packaging.

For at least a decade, experts have known that translucent packages were generally not as protective as opaque packages. Research showed that condoms stored in translucent packages and exposed to ultraviolet (UV) light may deteriorate in only a matter of hours, while opaque packages protected condoms from UV exposure. (Anonymous 1987)

A recent study of package integrity conducted by PATH and supported by USAID

and FHI showed convincingly that foil packaging offered the most protection from oxidative deterioration. The study found that plastic packaging is permeable to oxygen, while foil packaging is not. The study compared condoms stored for 36 to 48 months in a natural, tropical climate with those in a more temperate, climate-controlled setting. The condoms were tested yearly for strength, package integrity and oxygen content. Condoms from two U.S. manufacturers were used. (PATH)

The condoms packaged in only plastic cellophane deteriorated much faster than did those packaged in plastic-foil laminates. The decline in air burst pressure and volume from the air burst test were significantly higher for cellophane-packaged condoms, indicating the occurrence of oxidative deterioration in those condoms ($p < 0.0012$). This suggests that cellophane packaging is permeable to oxygen and thus may not prevent oxidative deterioration of condoms from occurring. A gas analysis of the two types of packaging found that oxygen content was consistently higher in the cellophane packages. (PATH)

A study focusing on the shelf life of condoms, conducted by PATH in conjunction with the FDA and FHI, found that condoms stored in impermeable, sealed foil packages have a shelf life beyond five years, even under tropical conditions. The study found that unpackaged condoms stored at high temperatures showed sharp decreases in air burst properties (both volume and pressure), rendering the condoms unfit for use within a three- to six-month period. (Free)

Currently, most studies by manufacturers of latex condoms that are naturally aged indicate that the shelf life of these condoms can be as long as five years, as long as they are not lubricated with spermicides. Spermicides have a shelf life of two to three years, however, thus shortening the shelf life of spermicidally-lubricated latex condoms.

Following a recent FDA ruling, condom manufacturers in the U.S. will be required to

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How A Latex Condom Is Made

by **Caroline E. Gilmore**

Latex comes primarily from the tropical rubber tree (*Hevea brasiliensis*), with the best quality found in Malaysia and Thailand. Latex is a natural elastomer and has the chemical name of *cis*-polyisoprene. Most other elastomers are synthetic. The liquid latex lies between the tree's bark and wood and is collected by making a series of slashes through the tree bark, which allows the latex to flow out of the tree. During collection, a small amount of ammonia is added to the raw latex to counteract the acid production of waste products from the bacteria that naturally feed on the latex and can cause the liquid latex to curdle. From this stage, latex is held in stainless steel tanks and processed with tools that are made only from stainless steel or other inert ingredients.

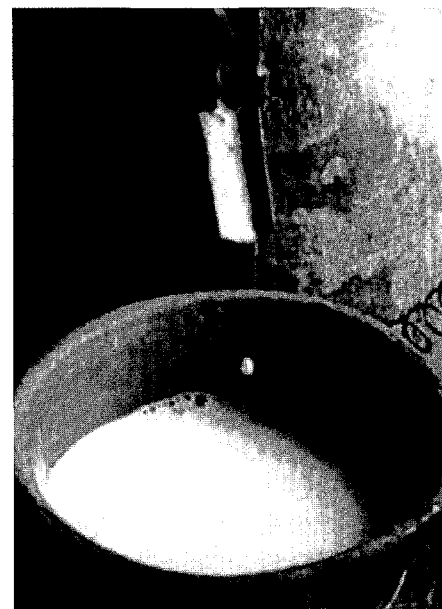
Liquid latex is actually a dispersion of rubber particles in water. Fresh raw latex consists of about 70 percent water and 30 percent rubber cells. The fresh latex is centrifuged, which concentrates it to approximately 60 percent solids. Concentrating latex reduces the cost of transport to the condom manufacturer and decreases the amount of time it takes to manufacture a condom. (Murphy)

The liquid latex is mixed with other chemicals to make a latex formulation for manufacturing. The latex formulation includes the liquid latex dispersion and various chemicals, including an antioxidant, a sulfur-based vulcanizing agent, and a vulcanizing accelerator. Accelerators are chemicals that increase both the rate and extent of cross-linking in the latex compound during vulcanization.

Latex condoms are produced by dipping plastic, ceramic, stainless-steel or glass mandrels mounted on a conveyor into a latex formulation.* The mandrel, most often glass, is dipped into the latex formulation in either a vertical or horizontal fashion, with virtually all manufacturers currently using a vertical dip. The mandrels go through a series of dips, rotating to spread the latex evenly. Between dips, each coat of latex is partially cured on the mandrel via hot-air drying in a carefully controlled tunnel-like oven on a conveyor system. Successive coats of latex are used to build the condom to the required thickness, with most manufacturers using two dips.

Brushes or water jets then roll up a section of the condom's open end to form the rim roll at the base of the condom, which stays in place because the rolled latex adheres to itself. Then, the condoms, still on mandrels, are dipped into one or more hot baths of either water or a caustic agent such as sodium hydroxide or potassium hydroxide. This removes some of the latex proteins from the condom, a process called leaching. Another round of curing is completed in a drying tunnel.

The condoms are then removed from the mandrels using brushes or water jets, placed in an appliance similar to a clothes washing machine and washed with a powder slurry, usually cornstarch. After washing, the condoms are dried in a large appliance similar to a clothes dryer, which removes the liquid but leaves the dry powder on the condom to serve as a dry lubricant for further processing.



Liquid latex from a rubber tree.

Mayer Laboratories, Inc.

* Latex is a liquid, and the condom material is technically "latex rubber." In this monograph, as in common usage, we refer to the "latex" condom rather than the "latex rubber" condom.

Each condom is tested electronically for the presence of any holes. The condom is then rolled into its final configuration and placed between two layers of packaging material. If the condom is to be lubricated, a specified amount of lubricant and/or spermicide is put on the condom, and the two layers of packaging are then sealed.

Most are lubricated with silicone or a water-based lubricant, which may or may not include a spermicide. The most commonly used spermicide is N-9, a water-soluble detergent (surfactant) that interacts with the cell membranes, killing sperm, bacteria and some viruses.

Latex condoms are manufactured in different shapes, textures, colors, thicknesses, widths and lengths. A reservoir tip may or may not be included at the closed end of the condom. Some condom surfaces are smooth, while some are textured, sometimes in a design on the outside or inside surface. Most condoms are a dull opaque tan, although some are colored. Some condoms are manufactured with scent, flavoring (strawberry, mint and others), or other features.

Currently the two most common condom shapes are straight-sided and contoured/form-fitting. A straight-sided condom has basically the same diameter at its open and closed ends. A contoured condom is similar to a straight-sided condom, but with a slightly smaller width just below where the head of the penis would be. A third shape is tapered from the closed end to a smaller diameter at the open end, and a fourth has a bulbous tip at the

closed end. The open-end diameter is about the same size for all shapes.

Condom dimensions vary. In terms of film thickness, almost all latex condoms are between 0.01 mm and 0.09 mm. Those made in the U.S. are generally from 0.03 mm to 0.07 mm (Hatcher) while those in Japan are generally 0.01 mm to 0.03 mm. (Concar) The lay-flat widths, corresponding to diameter, range from 47 mm to 55 mm, with most measuring 52 mm. Latex condom lengths range from 160 mm to 210 mm, with the majority measuring between 170 mm and 190 mm.

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support their shelf life labels with laboratory test data. Beginning in March 1998, the labeling of latex condoms produced in the U.S. must contain an expiration date based upon the results of physical and mechanical testing performed after exposing naturally-aged and accelerated-aged condoms to varying conditions.

Latex Allergies

Research in recent years has raised concern about sensitivity and allergic reactions to latex condoms due to proteins in natural latex, to chemicals added to latex formulations, and to spermicides added to lubricants at the factory. Latex allergies are quite rare among the general population, however. Concerns

about latex allergies should not inhibit sexually active people who are at risk of exposure to STDs from using condoms, since the risks associated with unprotected sexual contact are far greater than those from exposure to latex.

Some proteins found in natural rubber latex can cause sensitivity or allergic reactions. Condom manufacturers remove many of these natural proteins using a washing process called leaching. Leaching is done by dipping the condom in a series of baths, which usually contain hot water or a hot caustic solution. Leaching not only removes latex proteins, but may remove other components of latex as well.

The release of latex proteins can also result from interactions between the latex device and other chemicals, including the accelerators, antioxidants and dyes added to the latex formulation. (Rademaker; Turjanmaa) Accelerators, which increase latex cross-linking during vulcanization, can also cause allergic reactions.

Sensitivities or allergies usually develop gradually when mucosal and/or peritoneal surfaces come into repeated contact with protein allergens released from natural rubber latex. (Stratton; Deusch) The vagina and opening of the penis are both mucosal surfaces.

No studies have found that latex condoms result in high allergy rates. Among those allergies due to latex condom exposure, none has been extremely serious. Most allergic reactions to latex are minor, such as redness, itching, swollen and watering eyes, and swelling or inflammation, which subside when latex exposure is withdrawn. (Tomazic; Sussman) Persons allergic to latex should consider using synthetic condoms if they are available.

Experts are concerned that allergies to latex condoms may be increasing in prevalence and severity. Latex allergies are already a serious and growing problem among certain populations, due to the increased use of latex examination gloves and catheters.

In 1993, as a result of increased latex sensitivities and allergies among its patients, a hospital in Springfield, MA, USA, stopped using any latex medical products, using synthetic products instead. Recently, several manufacturers have received FDA clearance for "low-protein" surgical/examination gloves which are made by including additional and more complex leaching processes. In 1997, the FDA ordered makers of all medical devices that contain natural rubber latex, which include condoms, to warn that the products may cause allergic reactions. The order also covered packaging of the devices.

The presence of nonoxynol-9 (N-9) in the lubricant of condoms may increase the amount of protein released from the latex. A recent study found that protein levels from latex condoms with N-9 in their lubricants were approximately five times higher than the protein levels from condoms without N-9 in their lubricants. (Stratton) By increasing the amount of protein released from latex, N-9 may actually trigger a latex protein reaction.

Some condom users may be sensitive or allergic to N-9 itself. (Fisher; Doods-Goonsens) These users must be sure to use only condoms that are not lubricated with spermicides. In the U.S. about one-third of the condoms lubricated at the factory contain spermicides, usually in the form of N-9.

Dry Powders

Concerns have also emerged about the possible toxic effects of talc and other substances used in the finishing process of the condom. Dry dusting powders help keep the rolled up latex condom from sticking to itself. To accomplish this, manufacturers have used cornstarch, talc, mica, calcium carbonate, silicon dioxide, magnesium carbonate, lycopodium, dry silicone and other powders, with cornstarch currently the most commonly used. (Kang)

Talc, a natural mineral magnesium silicate, is a good dry lubricant. When used for

cosmetic purposes, talc has not been a problem. (Wehner 1994, 1996) However, some experts think that when talc comes into contact with mucosal surfaces, it may be toxic. Because surgery usually involves contact with open or mucosal tissues and concerns were raised about the possible toxic effects of talc as a result of talc-coated surgical gloves, the use of talc on surgical gloves was stopped several years ago. (Kasper) When talc is used as a finishing powder on latex condoms, female partners of condom users may face a health risk due to the talc on the surface of latex condoms. The talc could migrate up the vagina, a mucosal surface, into the upper female reproductive tract, which may result in fallopian tube fibrosis with subsequent infertility. (Wehner 1996)

For many years, talc was the preferred dusting powder and was once commonly used in latex condoms manufacturing. The relevance of using talc on condoms seems to fall somewhere between the realms of surgery and cosmetic use, but enough concern has emerged to cause a shift away from using talc in condom manufacturing. Currently, while condom manufacturers report that they do not use talc, (Anonymous 1995) some appear to have continued using it.

Cornstarch has become the new industry standard for finishing. While not as problematic as talc, it too could pose problems. Cornstarch is a heavily cross-linked carbohydrate with particle sizes ranging from 1 to 3 microns in diameter. A recent study found that, when used with surgical/examination gloves, cornstarch binds to allergenic latex proteins, and the more cornstarch used, the more protein binding occurs. (Tomazic) The latex-protein contaminated cornstarch particles are small enough to become airborne and can expose any persons in the vicinity to the latex proteins via the lungs, mouth, nose, eyes and skin. Direct contact with latex is not necessary to initiate a reaction.

Any wet lubricant applied to condoms before packaging should decrease the amount

of airborne cornstarch. However, the cornstarch/latex protein complexes are more easily shed than latex proteins bound to the condom and could result in sensitivity or allergic reactions. Also, the airborne cornstarch/latex protein complexes remain an issue with unlubricated condoms.

Further research needs to be done to determine whether the dry powders currently used produce detrimental effects on users due to mucosal exposure. Researchers need to find new dry finishing powders, with one possibility being silicone powder. It has been widely used in other industries.

Conclusion

In recent years, better quality management, new research and the actions of manufacturers have led to a more reliable and safer latex condom.

Manufacturers now produce condoms that are more elastic with a chemical formulation that includes more antioxidants and better-controlled vulcanizates — all steps that ensure condoms do not deteriorate as readily as in previous years. To better protect latex condoms from deterioration, manufacturers are using more impermeable, foil packaging; switching from plastic to foil or foil laminate packaging; and focusing more attention on tight package seals. These steps help preserve the integrity of the condoms, even under the most adverse storage conditions.

On the health front, manufacturers have moved away from using talc as a finishing powder, due to concerns about its possible toxicity. More research is needed on the safety of using cornstarch, the current preferred powder for finishing, or on determining a safer finishing powder. New research on allergies to latex proteins has also focused more attention on better leaching of proteins from the natural latex. Manufacturers are now able to produce condoms with less latex protein. More research is also needed to determine whether adding spermicides to the lubricant at the factory could result in more allergic reactions to latex.

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Standards, Specifications and Tests

**by William P. Schellstede, Eli J. Carter
and William R. Finger**

The emergence of the AIDS pandemic focused high-level scientific attention on condoms for the first time. When the U.S. Surgeon General recommended condoms to the U.S. public, for example, government officials and scientists went into libraries and laboratories to see what data supported such recommendations. Were there any tests that proved its reliability?

In the late 1980s, research began to yield more reliable guidance on condom performance. The most informed scientific debate often took place in the forum of standards organizations, involving research institutions, major buyers of condoms, the manufacturers and academics. Standards organizations provide technical definition for products manufactured in their respective jurisdiction.

Until these debates, standards for manufacturing condoms were determined almost exclusively by industry practices. Manufacturers relied on their own tests, on consumer demand and on specifications from large buyers such as the military. The manufacturers tested for uniformity in condom dimensions, holes and variations in the strength of the product. However, regulatory bodies did little monitoring of condom production, and no worldwide standards on quality assurance existed.

As better understanding of condom tests emerged, regulatory bodies carried out a more thorough examination of manufacturing practices, and test data received more scrutiny by major condom procurement agencies such as USAID. Gradually over the last 20 years, standards for condom production have been

tightened and refined, with some countries establishing rules regarding condom quality. Also, greater uniformity among standards has evolved throughout the world.

Currently, six primary laboratory tests are used to assure the quality of new latex condoms at the factory: condom dimensions, package integrity, lubricant quantity, leakage, tensile properties and air burst properties. Some of these are also used to test the quality of condoms after being transported, stored in the field or artificially aged in laboratories.

Tests are able to measure directly condom dimensions, package integrity, lubricant quantity and leakage. The tensile and air burst tests measure various strength properties of latex film. In addition, an oven-conditioning process is used to simulate the aging of condoms. Air burst and/or tensile tests are then used to assess the changes in various strength properties of these artificially aged condoms. (See page 50 for a summary description of these tests.)

This chapter first discusses the major standard-setting agencies, procurement specifications and regulatory actions. It then summarizes the function of the major laboratory tests and concludes with proposed changes to the standards.

Standard-setting Agencies

Worldwide, there are three major agencies that have established condom manufacturing standards: the International Organization for Standardization (ISO), the Comité Européen de Normalisation (CEN) and the American Society for Testing and Materials (ASTM).

Standards set by these agencies are key benchmarks for manufacturers, government regulators and large purchasers.

The standards published by these authorities are concerned primarily with safety and the integrity of manufactured products. Standards establish minimum acceptable quality levels for a product, in this case, the latex condom. In some circumstances, standards are required by law. In other situations, standards serve as guidelines for the manufacturers. If random samples from a batch of condoms pass a standard, the batch is considered acceptable for the market.

The ISO is a worldwide federation of national standards bodies, called "member bodies." Each member body has one vote. Representatives of manufacturers, regulators and research institutions from a single country must reach a consensus among themselves regarding how they will cast their single vote. Countries can choose to be represented on the ISO technical committee that develops standards. Proposed changes in standards are circulated to member bodies for discussion. Adoption of an international standard requires approval by at least 75 percent of member bodies casting a vote; currently 20 to 25 countries cast votes on condom issues. A slow, deliberative body, the ISO sometimes takes years to make a change in standards.

The CEN establishes the standards for the 18 member national bodies in the European community. In theory, the CEN has the same standards as the ISO. However, the condom standard currently includes some requirements that are different from those in the ISO condom standard.

The ASTM sets standards for a broad range of products manufactured in the United States, including condoms. It is a voluntary, membership body, composed of manufacturers, purchasing agents, raw material suppliers, research institutes, individuals and other groups. Each member has one vote regarding changes in condom standards.

The ASTM, ISO and CEN standards all

affect condom quality worldwide because many of the condoms distributed in developing countries are manufactured in the United States, Europe and Asia.

Procurement Specifications and Regulatory Actions

Procurement specifications are established by the major condom buyers. While standards focus on the manufactured product, specifications stipulate requirements for condoms that reach the consumer. Specifications are designed to ensure that condoms are safe, effective and acceptable to a particular set of users. They specify such issues as shape, color and packaging, and include details on quantity and delivery schedules. Major purchasers of condoms develop their own specifications, guided primarily by the ISO and ASTM standards. Two major condom procurement specifications are used as models by countries throughout the world, those of WHO and of USAID.

Government regulatory agencies have still another emphasis: to ensure that various laws and regulations are being met and that the condom is safe. If a condom is faulty, it could result in an unintended pregnancy or transmission of a sexually transmitted infection.

Regulators therefore monitor the accuracy of claims made by manufacturers on consumer labeling, inspect manufacturing facilities, test domestically manufactured and imported condoms for quality, and test condoms already on the market. Regulatory agencies include the FDA, comparable agencies in other countries, and government agencies regulating imports and exports.

The FDA currently uses the ASTM standard for condoms as a basis for audits of manufacturers, product recalls and injunctions against manufacturers, but is considering using some elements of the ISO standard. Many developing countries rely on the ISO standard and WHO specifications for testing condoms that are entering their countries. For example, India and Indonesia have adopted

*Currently, six
primary laboratory
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assure the quality of
new latex condoms
at the factory.*

the WHO specifications as their basis for regulating imports.

While latex condom standards among the major standards and specifications are becoming more uniform, there are still significant differences (see Table 5-1). The most significant differences are discussed below.

Traditional Laboratory Tests

The traditional laboratory tests measure dimensions, leakage ("freedom from holes") and tensile properties.

Dimensions. This group of tests measures condom width, thickness and length. The major difference among the international authorities concerns thickness. Procurement agencies emphasize thickness more than the standard-setting agencies, believing this to be important for consumer safety. USAID specifications require a minimum thickness of .05 mm, and the condoms they buy have a typical thickness of about .06 mm. WHO requires a thickness range of .04 mm to .08 mm. The ASTM standard calls for a minimum of .03 mm, while both ISO and CEN have no thickness requirement, allowing "ultra-thin" condoms manufactured in Japan to comply with those standards.

The minimum length requirement, which does not include the reservoir tip, ranges from 160 mm to 180 mm. The width requirement is generally 50 mm to 54 mm. WHO and USAID specifications have two range requirements, for standard width and for smaller-width condoms, which are designed for targeted markets, primarily in Asia.

Leakage ("Freedom from Holes").

Leakage tests are used both during the manufacturing process and by independent laboratories testing the finished product for quality assurance purposes.

Manufacturers screen every condom during the manufacturing process for tiny pinholes or weak spots, using either a "dry" or "wet" screening method. The dry method involves placing the condom on a metal mandrel and inducing an electrical charge

across the condom; a hole allows the current to pass, indicating a faulty condom. The wet approach immerses the condom in an electrolyte, saline solution, with an electric current signal indicating if any holes are present.

Independent laboratories testing selected condoms from batches for quality assurance use either the "hang" or the "hang/roll" method, described on page 50. (Some manufacturers also use these methods.) ISO, CEN and WHO require the hang/roll method. ASTM and USAID require only the hang method. The hang/roll method is more capable of detecting holes that leak tiny amounts of water undetected by the human eye. Even so, both tests are limited to visual detection.

While experts consider the visual test acceptable, they would like to find a more reliable and reproducible test that is independent of the technician's judgment. An electronic detection approach could be used, but would require complex apparatus. In monitoring condom imports, a few countries currently use an electronic wet test similar to the one used during the manufacturing process.

Tensile Properties. Used in many industries, tensile tests measure the extent to which a material changes shape in relation to an applied force. The condom tensile test stretches a cross-sectional piece of latex film, a ring cut from the mid-section of the condom, until it breaks. It measures three properties of the latex: the force it takes to break the ring of latex, the maximum amount of extension before breaking (called percent elongation), and the tensile breaking strength. The tensile measurements were designed to monitor quality and uniformity of manufacturing a latex product.

The tensile test has limitations in terms of predicting how well condoms function in human use; it was not designed for this purpose. The portion of the condom being tested is enclosed within the roll of the packaged condom and is therefore partially if not completely protected from exposure to

Table 5-1. Comparison of International Latex Condom Standards/Specifications, 1997

	ISO	CEN	ASTM	WHO		USAID	
Dimensions				(53 mm Width)	(49 mm Width)	(52 mm Width)	(49 mm Width)
Inspection Level/AQL	S-2; 4.0	min.10 Spls/NA	S-2; 4.0	S-2; 1.0	S-2; 1.0	S-2; 2.5	S-2; 2.5
Length, mm	160 min.	170 min.	160 min.	180 min.	170 min.	170 min.	160 min.
Width, mm	50-54	50-54	54 max.	51-55	47-51	50 - 54	47 - 51
Thickness, mm	NA	NA	.03 min.	.04-.08	.04-.08	.05 min.	.05 min.
Leakage/Freedom From Holes							
Inspection Level/AQL	G-I; .25 min.	315 Spls/.25	G-I; .40	G-I; .25		G-I; .40	
Test Method	Hang & Roll	Hang & Roll	Hang	Hang & Roll		Hang	
Defect Area	Exclude area >150 mm from closed end	Entire condom	Exclude area 25mm below open end	Exclude area 25 mm below open end		Exclude area 25mm below open end	
Air Burst							
Inspection Level/AQL	G-I; 1.0	G-I; 1.5	G-I; 1.5	G-I; 1.0		G-I;1.5 (Double)	
Volume, L	16.0 min.	18.0 min.	16.0 min.	18.0 min.		16.0 min.	
Pressure, kPa	1.0 min.	1.0 min.	1.0 min.	1.0 min.		1.0 min.	
Note:			(Exclude leakers)	(Exclude leakers)		(Exclude leakers)	
Air Burst (after 2 Days @ 70°C)							
Requirements	Same as before aging	Not required	Not required	Not required		Same as before aging	
Air Burst (after 7 Days @ 70°C)							
Inspection Level	Not required	Not required	Not required	min. 80 Spls		Not required	
Volume, L				27.0 min. (mean)			
Pressure, kPa				1.0 min.			
Tensile							
Inspection Level/AQL	Not required	min.13 Spls/NA	Not required	Not required		S-2; 2.5	
Force, N		39 (median)				35 min.	
Breaking Str.,MPa		NA				17 min.	
% Elongation		700 (median)				650 min.	
Tensile (after 2 Days @ 70°C)							
Inspection Level	Not required	13 Spls	Not required	Not required		Not required	
Force, N		39 (median)					
% Elongation		700 (median)					
Tensile (after 7 Days @ 70°C)							
Inspection Level	Not required	Not required	Not required	Not required		S-2	
Force, N						35 (mean)	
Breaking Str.,MPa						17 (mean)	
% Elongation						650 (mean)	
Package Integrity							
Inspection Level/AQL	Not required	Not required	S-3; 2.5	S-3; 2.5		S-3; 2.5	
Lubricant Quantity							
Inspection Level/AQL	Not required	Not required	Not required	S-2, 4.0		S-2; 1.5	
Quantity, mg				350 - 550		250 min.	

Inspection Levels – G (general sampling level); S (special sampling level). The higher the number, the larger the sample.
AQL – Acceptable Quality Level; Spls – Sample Size

oxygen and ozone. Thus, the sample used for tensile testing would not be expected to deteriorate as much as the condom tip, which is not protected within the roll.

Also, the tensile test measures the condom in an area and direction that are not the most critical to condom performance during use. The middle section of the condom is not subjected to forces as strong as those either at the base (open end) or tip (closed end) of a condom. During condom donning, the tip-end of the rolled condom is stretched or forced until it fits over the penis. After unrolling the condom its entire length, it is the base of the condom that is manipulated to place it properly. In removing the condom, the tip and/or base again receive the most pressure.

In the 1980s, USAID began more rigorous testing of condoms that it purchased for distribution in developing countries, including investigating more closely complaints about condom breakage from developing countries that received USAID commodities. The condoms from apparently defective batches continued to pass the standards for the tensile test. When using the air burst test and the hang water leak test, however, the tip of the condom broke easily, which suggested that these tests might be more predictive of breakage in human use.

Most experts gradually agreed that the tensile test did not adequately measure deterioration

or other factors that could lead to breakage in human use. In 1996, both the ASTM and the ISO dropped the tensile test from their standards. WHO also dropped the tensile test. As of 1997, USAID and CEN still require it because the test does provide valuable information on the quality of condoms at the point of production. The tensile test gives direct

evidence that the latex has been formulated and vulcanized correctly. It has also been a useful guide in the development of alternative condom materials.

Air Burst Test

In the late 1970s, researchers began to use the air burst test, believing it might be more predictive of condom performance in human use than the tensile test. The air burst test inflates the entire condom like a balloon, stretching all of the latex until it bursts. Hence, it tests the strength of the entire product, not just a portion of the condom. The test measures the maximum amount of air the condom can hold before breaking as well as the air pressure level inside the condom when it breaks.

By 1986, two published scientific articles (discussed in Chapter 6) suggested that the results of the air burst test did correlate with breakage in human use. (Free 1980, 1986) In 1990, after some 15 years of deliberation, ISO issued its first condom standard, which included both the air burst and tensile tests. A central reason for the long delay was the debate over testing methodology and acceptance limits of the air burst test. In 1990 USAID adopted the ISO air burst test into its procurement specifications.

The U.S.-based ASTM was slower to adopt the air burst test, apparently because of the limited research data correlating it with human breakage. In 1992, however, two published studies pointed out weaknesses in the ASTM standard. One found breakage rates ranging from 7 percent to 13 percent in three countries using batches of condoms that had passed the ASTM standard. The study concluded that the laboratory tests used in the ASTM standard could not reliably predict condom performance during human use. (Russell-Brown) The other study found that measurements from the air burst test, as well as the percent elongation measurement from the tensile test, were highly predictive of condom breakage in human use. (Steiner)



Air burst test inflates condom like a balloon.

Caroline E. Gilmore/FHI

In 1993, ASTM included the air burst test in the standard but did not establish minimum acceptance criteria. In 1996, after further studies by manufacturers and research groups, the ASTM adopted acceptance criteria.

The current air burst criteria in the international standards and specifications vary primarily on minimum air volume. CEN and WHO minimums are 18 liters (L), with ISO, ASTM and USAID at 16 L. When USAID reviewed its specifications prior to soliciting bids for 1996-98, it considered raising its minimum to 18 L. In discussions with manufacturers, concerns arose that making this change could result in other changes, such as a slightly thinner condom that would also be more expensive. In the absence of compelling data indicating that 18 L would ensure a product with improved performance, such as reduced breakage, and given the additional concerns, USAID retained the 16 L requirement.

The air burst test has several drawbacks. First, because it inflates the entire condom, the condom breaks when its weakest point gives way to the air pressure. If this is in the thinnest part of the condom, the test is not sensitive to defects in the thicker regions of the condom, which might receive more pressure during intercourse. For example, for condoms that are manufactured with thicker latex at the closed end, the air burst test may not be sensitive to weaknesses there and hence, not predictive of breakage in human use. Several unpublished studies have found that while a batch of condoms can have very low breakage rates in use, the batch may have a relatively poor air burst performance.

The air burst test protocols exempt the portion of the condom very close to the open end, but the air burst test might be more

Table 5-2. Laboratory Tests for Determining Condom Quality

Test	Purpose	Equipment	Limitations
Leakage/Freedom from Holes	To detect holes that may allow passage of sperm or STD organisms	Apparatus capable of vertically suspending condoms filled with water	Limited to visual detection
Air Burst	To measure condom strength	Apparatus capable of inflating 150 mm of the condom from the closed end	Requires skilled lab technicians, precise equipment calibration and maintenance
Tensile	To measure condom strength and cure	Standard tensile tester equipped with ring test fixture	Tests only a small section of condom
Lubricant Quantity	To determine the amount of lubricant and other dressing materials applied to the condom	Analytical balance, 200 ml containers	Accuracy dependent upon technical experience and technique
Package Integrity	To ensure that the package is properly sealed and free of holes and voids	Wet or dry vacuum	Requires trained lab technicians
Dimension	To measure condom size (width, length, thickness)	Graduated mandrel, ruler, thickness gage	Requires trained lab technicians
Oven Aging	To serve as a surrogate for natural aging before air burst and tensile testing	Convection oven or environmental chamber capable of maintaining a constant temperature of 70°C for up to 7 days	Not necessarily predictable of storage conditions

predictive of breakage if it focused more directly on the closed end. A better test might be the so-called "short-stem" air burst test, which blows air into a smaller part of the condom near the closed end (see page 52 for more).

Another limitation of air burst testing is that variations occur among laboratory testing facilities. Hence, unless condoms are tested at the same laboratory using the same method, personnel and equipment, test results may not be comparable. To address this concern, in 1993 USAID began sponsoring an international

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Major Laboratory Tests for Condom Quality

by William P. Schellstede, Eli J. Carter
and William R. Finger

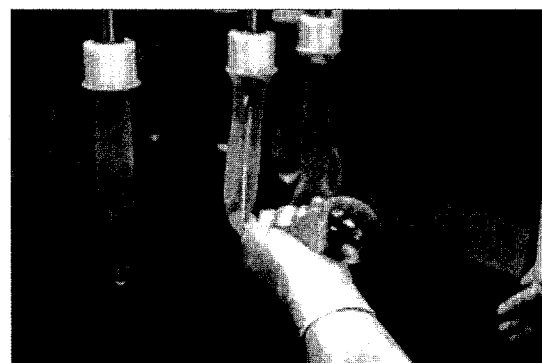
Dimensions. To measure length, the condom is stretched slightly (5 percent to 10 percent) to smooth out wrinkles caused by having been rolled up and then hung over a graduated mandrel. The width is measured at a right angle to the length of the condom, when it is unrolled and laid flat without any creases. Typically, three thickness measurements are made for each sample condom, and an average is determined. In the tests, lubricants must be removed, and powders are added to avoid sticking.

Caroline E. Gilmore/FHI



Thickness measurement.

Leakage ("Freedom from Holes"). In the hang method, the condom is filled with water, usually while hanging vertically, and a technician observes for leaks. In the hang/roll approach, a technician takes the water-filled condom from the hanging position, ties the



Caroline E. Gilmore/FHI

Leakage test.

end, and rolls it across an absorbent paper looking for water on the paper. By using a guiding device, the test operator can apply equal pressure across the condom, so that the entire condom surface touches the paper.

Tensile. A 20 mm-wide sample is cut from the mid-section of the condom. The test stretches this cross-sectional piece (ring) of latex until it breaks, using a constant rate of circular motion and applying pressure equally to the entire piece of condom. The test measures the force it takes to break the latex (breaking force, in Newtons); the length of the latex piece when it breaks (percent elongation, percent increase from initial to final circumference); and tensile breaking strength (megapascals), a calculation using the thickness of the latex and the Newtons of breaking force.

Air Burst. The test inflates the condom like a balloon and measures the volume of air and air pressure needed to burst it. A technician unrolls the condom manually and clamps it on a stem, leaving about 150 mm to be inflated. The apparatus should inflate the condom with clean, oil-free and moisture-free air at a specified rate. Variables in measurements include barometric readings, types of clamps used, manual or computer recording of data, and airflow rates, which may require a conversion calculation.

Package Integrity. A packaged condom is put in a vacuum system, either in water or in a dry, bell chamber. In the wet system, after one minute of vacuum stress, bubbles appear if there are holes in the package or the seal is defective. Placed in a dry vacuum for one minute, the package should inflate and remain inflated to pass the test.

Lubricant Quantity. To determine the amount of lubricant used in a pre-lubricated condom, the test measures separately and in various combinations the weight of the packaged condom, the condom with lubricant,

the lubricant on the condom, the lubricant in the package, the cleaned condom and the cleaned package.

Oven Test. Seeking to simulate the aging process, the test is intended to provide some indication of how stable the product will be after being stored. After being artificially aged in an oven at an elevated temperature for a designated period of time, the tensile and/or air burst tests are performed. Results are compared with the base-line data to determine the degree of product deterioration.

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collaborative effort among condom testing laboratories called the Condom Inflation Test Network (CITNET), with PATH coordinating the project. CITNET provides a continuing mechanism whereby condom air burst test systems at manufacturing sites, government agencies and independent laboratories can be checked against one another to minimize inter-laboratory and inter-system variation.

CITNET participants include labs in the United States (Alabama, Massachusetts, North Carolina, Ohio and Washington), Australia, England, Malaysia, Sweden and Zimbabwe. CITNET participation is voluntary and all data are available to all participants. Condoms from the same lot are sent to participating labs with precisely the same testing protocol. The labs test the condoms and return results to the CITNET coordinator. This monitoring process has resulted in a significant reduction in air burst volume variation among test systems over time and has led to suggestions for system re-engineering to further decrease testing variations.

Testing for Deterioration

In the late 1980s, researchers began to test condoms stored in warehouses to assess the importance of condom deterioration. Manufac-

turers knew that latex deteriorated or "aged" gradually over time and that certain storage conditions, such as intense heat, humidity or moisture, could accelerate the aging process.

One way to slow the aging process of condoms and to ensure product stability was to increase attention to packaging. Concerned that consumers have confidence in receiving a condom in good condition, major buyers including WHO and USAID added a package integrity test to their specifications. This test subjects the package seal to stress under a vacuum seal. ASTM also added this test to its standard, although ISO and CEN have not.

The amount of lubricant in the package can also affect oxidation and thus slow deterioration. (Free 1996) Only the procurement agencies, WHO and USAID, have required this test. USAID requires a minimum of 250 milligrams (mg), and the average is generally about 400 mg. WHO requires 350 mg to 550 mg.

As attention to storage conditions increased, a method of artificially aging condoms assumed more importance. A so-called "oven test" was designed to mimic natural deterioration. Current standards and specifications differ substantially regarding the length of the aging period, the temperatures at which the

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New Tests for Product Development

by Eli J. Carter and William R. Finger

Coital Model. Recent laboratory studies evaluating the permeability of male and female condoms to viruses have used several types of apparatus that attempt to simulate physiologic conditions of intercourse. In two studies, the tests sent a microsphere suspension along the center of a penile form, covered with a condom. The suspension expanded the condom and was left there for 30 minutes. The test was designed to mimic the expected temperature, peak pressure and stretch of the condom during intercourse. (Lytle; Carey) The model did not incorporate motion, because, according to the Carey study, there are insufficient data to enable meaningful modeling of the dynamic aspects of coitus. Also, they assumed that the stretching of the pores of the condom came primarily from stretching the condom over the penis, not from the motion of coitus.

Two earlier studies did use motion in their coital models. In one study, a suspension of HIV was dispensed in an untreated condom, which was then placed over a 20 milliliter (ml) disposable syringe and attached with a knot at the top of the plunger to achieve water tightness. The plunger and the condom were then put in the barrel of the syringe. The plunger was moved vigorously up to 50 times as a means of putting pressure on the condom to determine the effect on permeability. (Van de Perre)

To test permeability of a female condom to STDs, 2 ml of virus suspension, which included HIV, was placed inside a female condom. That condom was then placed inside a second female condom, minus the insertion ring. A 35 ml plastic syringe case was inserted into the inner condom to serve as an artificial

penis. The entire apparatus was then placed into a close-fitting foam model, designed to serve as an artificial vagina. The apparatus was plunged up and down 50 times. While the authors found the approach sufficient for testing impermeability, they also cautioned that the laboratory model has drawbacks for simulating intercourse. (Drew)

Dynamic Mechanical Analysis (DMA).

This is a technique to characterize polymers, such as latex rubber, and other materials whose mechanical behavior changes with temperature, under force/strain and due to other variables. The technique usually involves vibrating a sample at a certain frequency and measuring the response. Latex rubber is known as a "viscoelastic" material; i.e., it has a "viscous" or damping component and an "elastic" or springy component. DMA measures the combined viscoelastic response and separates the response into its components. The response of these components changes with the frequency of vibration and with temperature. For example, the children's toy called Silly Putty, which is a silicone rubber, becomes solid if it is very cold but flows under its own weight in a warm room. If pulled quickly, it fractures; if pulled slowly, it stretches. Analogous phenomena occur in latex rubber.

Since DMA measures how a material stores energy (the viscous component) and transmits energy (the elastic component), it may have some predictive value with respect to breakage and/or slippage. This testing technique is widely used in the polymer industry but has not been extensively considered for condom testing.

Fourier Transform Infrared Spectroscopy (FTIR). This is a test of the chemical elements of a product, its chemical building blocks. For the condom, FTIR can give an indication of

impurities, state of oxidation, the composition of plastic condoms, and other information. Some think of it as the chemical "fingerprint" of the condom. Current tests for pinholes and weak spots in the rubber look at mechanical properties of the condom, not the chemical properties. FTIR could be used, for example, to assess the extent of oxidation in condoms that have been stored for a long time.

The advantage of the FTIR is that it is fast and inexpensive. The disadvantage is that it is not very sensitive. It requires at least 1 percent impurities to work well, and lower levels of impurities are hard to detect. The technique is not widely used in the condom industry even though it has been available for about 20 years. It is widely used in the chemical and pharmaceutical industries for quality control and structure determination.

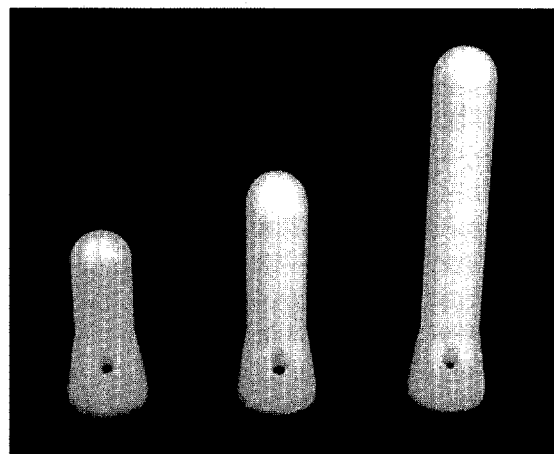
Short-Stem Air Burst Test. In the current air burst test, the condom is clamped on a mandrel-like device near the open end, about 150 mm from the tip. The standard condom is 160 to 180 mm long. Thus the test inflates virtually the entire condom with air, inflating the condom like a balloon. This obviously does not simulate human use and does not concentrate the air pressure where the latex experiences the most stress and strain. Due to thrusting, friction and ejaculation, the tip of the condom probably receives more pressure than do the sides.

A "short-stem" test has been developed to concentrate the air pressure more towards the closed end of the condom, so as to simulate more closely the type of stress and strain the latex experiences in human use. This test would focus on the closed half of the condom, shortening the length tested from 150 mm to as short as 75 mm. FHI is conducting a study that compares the results of the standard air burst test and the short-stem test to condom breakage during human use, using stem lengths of 75 mm, 100 mm and 150 mm.

Tear Test. This test measures the force necessary to cause a tear in the latex. In 1994,

ASTM adopted a standard for a tear test for plastic film and thin sheeting, called the "tear-propagation resistance" test using a single-tear method. In this test, a thin plastic film is attached to a machine that separates the material. The force necessary to cause the tear is interpreted from a chart that measures the load of force and the time taken to cause a tear, called a "load-time" chart. The line graph in these charts clearly distinguishes a "low-extensible" from a "high-extensible" film.

There is much more resistance to tearing in the high-extensible film. The standard cautions, however, that performance during actual use may not necessarily correlate with data from this test method. It also points out that data from specimens of dissimilar thickness are usually not comparable. Experts do not agree on whether the tear test can be useful for latex rubber.



Different condom mandrel lengths.

Caroline E. Gilmore/FHI

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product is conditioned, which tests to use in measuring the aged condom, and minimum acceptance requirements.

ISO and USAID require a condom aged for two days at 70° C to undergo the air burst test and meet the same minimum requirements as before aging, 16 L of volume and 1.0 kilopascals of pressure. Normally, the mean volume for a batch of new condoms is much higher than the minimum, from 25 L to 40 L. WHO requires 27 L minimum mean burst volume for the batch after seven days of oven conditioning at 70° C, with the same 1.0 kilopascals of pressure.

USAID also includes a tensile test after seven days at 70° C. The ASTM is currently considering an oven conditioning standard but does not have clear data for developing a protocol. Experts are debating whether aging time periods and temperature ranges in the oven test have any correlation to real-time aging, calling into question the aging protocols now in use. Research is continuing to find better ways to predict accurately the stability of the product as it ages.

Proposed Changes in Standards

Among the changes under discussion are: tightening the acceptance criteria for the leakage test, improving the package integrity test and adjusting the air burst test.

Tightening Acceptance Criteria for Leakage Test. Authorities are concerned about limiting the number and size of pinholes that could allow sperm, bacteria or viruses to escape through the condom. Water molecules are smaller than even HIV molecules, so using a water test can address the concern — if the test is tight enough. There are several ways to tighten the current protocols: to require the hang/roll method rather than the hang approach alone, and to set more stringent acceptable quality levels (AQL). The AQL indicates a calculation that allows a certain number of defective condoms in a given batch; the AQL is not a percentage measurement.

For the leakage test, ISO, CEN and WHO have a tighter AQL, a limit of 0.25, compared to the ASTM and USAID, which have an AQL of 0.40. ASTM and USAID are considering tightening their AQL to 0.25 as well.

The AQL level and number of allowable defects depends on the sample size tested. For example, in the leakage test, in a group of 315 condoms selected for testing from a batch of 150,001 to 500,000 manufactured condoms (a standard test size), a 0.40 AQL allows acceptance of the entire batch if three condoms fail the test; if four fail, the entire batch is rejected. Tightening the AQL for leakage to 0.25 would bring the acceptable number of failures for this batch down from three condoms to two in the sample tested — i.e., the whole batch is rejected if there are three defective condoms in the sample.

Theoretically, either change may tighten the standard. But no research has been done to show that such a tighter standard would result in less condom failure in use.

Improving Package Integrity Test. Recent research has found that condoms with no packaging or with plastic film packaging deteriorate at a faster rate than do those packaged in foil. (Free 1996; PATH) WHO and USAID specifications now require that all condoms be packaged with aluminum-foil laminate. Other standards and specifications may also move to more specific packaging requirements.

Adjusting Air Burst Test. Various adjustments to the volume level are under consideration. Some proposals would raise the current limit while others would take a new approach, using allowable deviations rather than limits. Still others would adjust the air burst criteria used with the accelerated aging measurements. The current standards for new condoms rely on minimum limits, ranging from 16 L to 18 L. For the accelerated aging test, ISO and USAID require a minimum of 16 L volume, but the mean for a batch of condoms is usually much higher, 25 L to 40 L; WHO requires a minimum mean of 27 L.

Recent research recommended that in the accelerated aging measurements, the mean burst volume be no less than 30 L. (Free 1996) The limit might be slightly higher for condoms intended for use in hot climates and slightly lower for smaller condoms, the study recommended. Experts do not agree on whether and how high to raise the minimum burst volume. Although intuition suggests the higher the minimum, the better the product, most experts agree that there is not enough clinical data to justify raising the limit at this point. Several small studies are underway to test this hypothesis.

5

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Comparing Laboratory Tests with Human Use

**by Eli J. Carter and
Markus J. Steiner**

Laboratory tests have been used to measure condom quality since the 1930s, but not until the 1980s did scientists begin investigating the ability of these tests to predict condom failure during human use.

This chapter reviews the six published studies and two of the major unpublished studies that have compared laboratory tests with failure in human use. Ideally, laboratory tests would be able to predict condom failure during human use, and hence, could be used to determine which condoms would be most reliable. However, this research area lacks studies of sufficient size and quality to be able to say definitively which laboratory tests best correlate with failure rates in human use.

The published studies have involved a total of only 551 couples, more than half of them in one study (see Table 6-1). The studies do not reach the same conclusions. Moreover, new information about the importance of latex formulation (stress and strain properties), packaging and lubricants is now becoming available. These factors were generally not considered in the studies reviewed here. All of these studies have looked at condom breakage, although recent research has measured condom slippage as well. The term "condom failure" refers to condom breakage or complete slippage.

At this point, in the absence of definitive answers from research, there is no single indicator of potential failure in human use. The most reliable approach is to use several tests, in combination with the age of the condom. When monitoring condoms stored in

the field, FHI now tests condoms that have been stored for more than three years using the package integrity, air burst and lubricant quantity tests. The results of these tests in combination can help assess whether condoms in storage are reliable.

Methodological challenges have limited research in this field (see article, page 62). Also, user characteristics and condom design can vary, complicating the research process. Many factors can contribute to deterioration of latex over time, including light, excessive heat, high humidity, poor packaging, and the latex formulation. It is difficult in small-scale studies to measure the relative importance of the variables that influence condom breakage in human use. The reader needs to keep this important caveat in mind as the studies are summarized below.

The results of the six published studies are presented here in chronological order, in order to show the evolution of the thinking on these issues. Then two major unpublished studies are reviewed. The chapter concludes with a summary of what is known about the relationship of laboratory tests with performance in human use and what research questions we need to know more about.

It is important to note whether these studies were conducted using condoms from the same lot (also called a batch) or different lots. Condoms within a single lot are assumed to have less variability than condoms from multiple lots. A condom lot can be defined in various ways, using machinery, time of production and/or number of condoms. For example, USAID defines a condom lot as the

quantity produced on one production line during a 24-hour period. Lot sizes can vary from 7,200 to more than 500,000 condoms, because of a manufacturer's ability to control the process.

Artificial Aging

To simulate the impact of natural aging of condoms, laboratories typically age condoms artificially in chambers using heat (70° C). They sometimes use ultraviolet (UV) light or gamma radiation for the aging process, but these approaches are not representative of conditions likely to be encountered in natural aging and hence are not specified in any standards for condom testing. After artificial aging in heat chambers, laboratories subject these condoms to the air burst or tensile test, or both.

The first two published studies comparing laboratory test results to breakage in human use were coordinated by PATH and relied substantially on artificially aged condoms (UV light). In a 1980 study, six participants in the U.S. each received 36 condoms from one condom lot, divided into six groups of six condoms each (total of 216 condoms). Each condom group had been exposed to different levels of UV light. The study used the air burst test to measure condom strength of samples from each group before distributing the condoms to the participants. In 1980, no international standard included the air burst test, so the study was partly designed to assess the usefulness of this test. All used condoms were returned for inspection. (Free 1980)

Among the condoms that had deteriorated by less than 25 percent based on the results of the air burst test, not a single one broke during human use. While this was a small sample, the study concluded that the air burst test can effectively measure changes in condom strength. It also concluded that the minimum test standard being used in western laboratories was well above the minimum required for effective use; the study did not report the specific standards that were used.

In a 1986 study, PATH used artificially aged condoms as well as condoms aged in the field. The study had 130 participants in Indonesia use seven condoms each. Three of the condoms were new, but two of these three were artificially aged — one exposed to UV light for five hours, a second for 10 hours. The other four condoms in each group had been naturally aged under typical tropical conditions for about 42 months. All used condoms were returned and additional air burst testing was conducted with the unbroken condoms. (Free 1986)

While all condom groups had high breakage rates during human use, the naturally aged condoms had by far the highest rate: 49 percent. Those aged by 10 hours of UV light had a breakage rate of about 20 percent. If the air burst test correlated with breakage in human use, one would expect better air burst results among the artificially aged condoms since they had the lower breakage rates in



Technician measures condom in air burst test.

human use. However, this was not the case. The air burst inflation results were slightly lower for the condoms aged by UV light than for those stored in the field.

These findings illustrate how difficult it is in a small study to isolate those variables that

Alex Trend

Table 6-1. All Studies Published in Peer-Reviewed Journals 1980-1997 Comparing Human Use Breakage Rates and Laboratory Performance of Latex Condoms

Author	Site of Human Use	Sample: Size	Breakage Rates	Conclusions
Free 1980	USA	Family planning clients: N=6 (216 condoms from 1 lot)	0% to 30%	Burst test parameters can effectively and sensitively measure changes in condom strength.
Free 1986	Indonesia	Urban males: N=130 (910 condoms, no. of lots not clear in paper)	7%-49%	Condom breakage increases with increasing UV exposure; 10 hours UV exposure produced lower inflation properties than 42 months tropical aging, but breakage rates much higher in the latter.
Gerofi 1991	Australia	Clients, student health service: N=6 (11 condoms from 1 lot)	NA (numerator not provided)	Broken condoms and unbroken condoms had similar tensile value; relying only on tensile testing is not sufficient.
Russell-Brown 1992	Site 1: Barbados/ St. Lucia; Site 2: USA	Site 1: condom users: N=102; Site 2: advertised recruitment: N=45 (3,896 condoms from 1 lot – both sites)	Site 1: 10.1%-12.9% Site 2: 6.7%	Existing lab tests (prior to 1992) not sufficiently sensitive or well defined to predict condom performance reliably during human use; user behavior may be important in predicting breakage.
Steiner 1992	USA	Advertised recruitment: N=262 (4,589 condoms from 20 lots)	3.5% to 18.6%	The best laboratory tests for predicting reliable condoms were ultimate elongation ($R^2=.81$), CQI ($R^2=.74$) and air burst ($R^2=.69$). Surprisingly, age was the best predictor ($R^2=.92$).
Free 1996	Used USA human use data from Steiner 1992 study	See Steiner 1992	See Steiner 1992	Silicone lubricant, impermeable packaging and inclusion of antioxidants in the condom formulation can prevent or minimize aerobic breakdown of latex condoms.

could explain the breakage rates. The authors gave three possible explanations for the apparent inconsistency in the data. First, there was a different agent of deterioration between the two batches of condoms: heat/humidity among those stored in the field versus ultraviolet light among those artificially aged. Second, there could have been selective deterioration

of the condom tip in the UV light-exposed condoms, compared to a more generalized deterioration throughout the length of the condom in the field-aged group. Third, the field-aged condoms had an average 50 mm lay-flat width, a tighter fit than the 52 mm lay-flat width of the other condom batches, which could have led to more breakage.

Cross-Sectional Study

An FHI study published in 1992 tested condoms from 20 lots that differed in age, storage history and manufacturing dates. (Steiner) Four of the lots were new condoms obtained from four different U.S. manufacturers. The remaining 16 lots were from a single U.S. manufacturer and were recovered from warehouses overseas where they had been sent as part of the USAID family planning commodities program. The study used a "cross-sectional" approach, which means that condoms of different ages were collected at one point in time and tested in the lab as well as in human use. This contrasts with a prospective study design, discussed below, which follows condoms for a prescribed period of time and tests them at various points in time.

All of the condoms were sent to the PATH condom laboratory in Seattle, WA, USA, where random samples were evaluated using the tensile and air burst tests. The remaining condoms were then distributed to 300 study participants in North Carolina. Each couple was instructed to use 20 condoms during vaginal intercourse, one from each of the 20 lots, and to record their experience on data forms. The correlations between the lab tests and the human use breakage rates were then calculated.

Of the 300 couples, 262 completed the study, although some of them did not use all 20 condoms; a total of 4,589 condoms were used. Breakage rates ranged from 3.5 percent of new condoms to 18.6 percent for condoms that were almost seven years old and had been stored under adverse conditions.

The study found that the age of the condom, rather than any of the laboratory tests, was the best predictor of failure during human use, with a correlation coefficient (R^2) of 0.92. (The closer the correlation coefficient is to 1.0, the stronger the association between the two factors being measured.)

Several laboratory measurements were also closely related to condom breakage in

human use. The percent elongation from the tensile test had an R^2 of 0.81. Two outcomes from the air burst test followed: a measurement called condom quality index (CQI) had an R^2 of 0.74, and the percent of condoms failing the air burst volume test had an R^2 of 0.69. CQI is a mathematical treatment of air burst volume data to assess quality of condom stocks in storage. USAID used this measurement, among others, during the early 1990s to assess the quality of condom stock aged in the field.*

In this study, the high correlation of breakage during use with age may have resulted to some extent from the cross-sectional study design. The 16 lots of condoms from overseas storage were manufactured in different years by the same company and could have had different product attributes. During this time span, manufacturers and researchers learned a lot more about the product attributes that affect breakage, including the relationship of stress and strain formulation properties to oxidation and vulcanization, condom thickness, packaging and other issues discussed in Chapter 4. Hence, the very strong association between condom age and breakage rates may be partially due to the improved quality of the more recently manufactured condoms. That is, lower breakage rates of younger condoms may have been a function of more careful attention to the quality of the finished product rather than a function of a shorter aging period.

An additional problem with the cross-sectional study design was that information was not available on the transport and storage conditions of these condoms throughout their life. This limits the knowledge needed to assess all of the factors that might affect the quality of the condoms in storage.

However, the limitations may be outweighed by two strengths of the cross-sectional study design. It ensured that all lots were tested under similar conditions, because the laboratory tests were done at one point in time at one site. Also, having each couple use a

* The method of calculating CQI is explained in *Condom Quality Testing Handbook*, produced by PATH.

condom from each lot allowed for easy control of variation in sexual practices and user characteristics among couples.

Prospective Study

A study published in 1992 by the Population Council in collaboration with FHI used a prospective study design. Condoms from the same lot were tested in the laboratory in 1988 and shortly thereafter used by study participants in Barbados and St. Lucia, two small Caribbean countries. In 1990, the same lot was retested in the laboratory and used by U.S. participants. In each case, 50 male condom users were recruited at each site. (Russell-Brown)

In both 1988 and 1990, the condom lot passed ASTM requirements for tensile strength and percent elongation prior to the human use tests. It narrowly failed the ISO air burst test in 1988 and barely passed in 1990. The breakage rates during human use in Barbados and St. Lucia in 1988 were 12.9 percent and 10.1 percent, respectively. Two years later, the breakage rate was 6.7 percent among the U.S. participants.

The condom breakage rates in both 1988 and 1990 were unexpectedly high. Hence, the study concluded that existing laboratory tests as used with the current pass/fail standards were either not

sufficiently sensitive or not well-defined enough to predict reliably condom performance during human use. The study pointed out that the air burst tests revealed some failing values while the tensile tests did not. Hence, the study concluded that air burst test might be a more accurate indicator of condom quality than the tensile test.

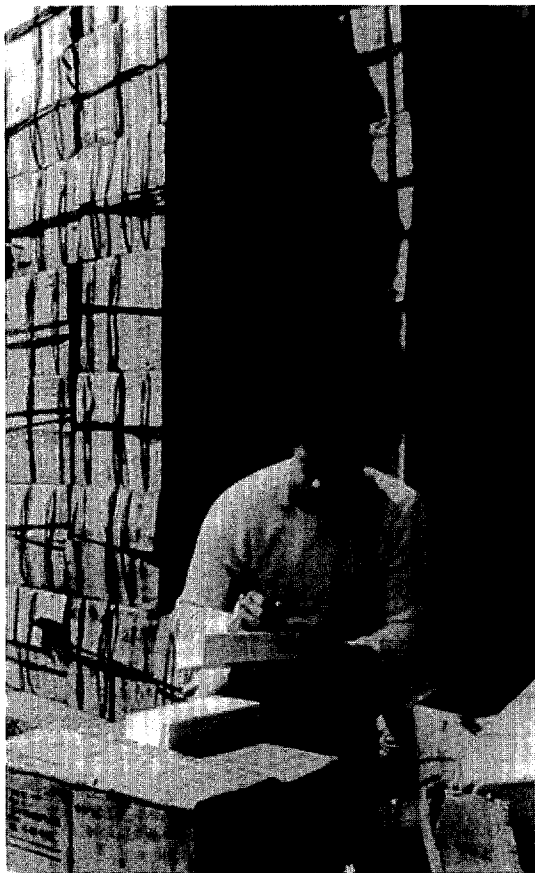
The study also concluded that sexual practices and user characteristics may be important factors in determining condom breakage. The higher breakage rates in the Caribbean countries, even though the condoms were two years younger, suggest that user behaviors or other characteristics are important factors. The study called for more research about behavioral differences among couples (see Chapter 3).

A prospective approach has several weaknesses in studying the correlation of laboratory tests with condom use. The variation in sexual practices and characteristics among couples are not controlled for from one time period to the next, because a new cohort of participants is enrolled at each time interval. Thus, any observed change in the failure rate of a condom lot may be due to a difference in the study population, not because of the characteristics of the condoms. Improvements in laboratory testing equipment and test methods may affect test data comparison over the span of the study as well. Finally, the studies take a long time to conduct, since the condoms are naturally aged.

Alternative Study Designs

During the past decade, PATH, in collaboration with the FDA, conducted a series of studies looking at how well laboratory tests predict shelf life of condoms. (Free 1996) In one of the studies, condoms from a single production lot were stored in warehouses in Pakistan, Thailand and Mexico and sampled periodically for laboratory testing. This aspect of the study incorporated a prospective design; that is, it tested condoms from the same lot at different points in time.

Son Balogh/FHI



Monitoring condoms in storage.

The study compared the mean air burst volume of these condoms, collected prospectively, with the data from the 1992 FHI study, collected cross-sectionally. (Steiner) The air burst volumes of the condoms in the two studies decreased over time in a similar fashion. Although this study did not collect any human-use breakage data, the study nonetheless concluded that the air burst test is a reliable way to detect changes in stored condoms due to shelf vulcanization and oxidation, both of which could reduce resistance to breakage during human use.

A small study published in 1991 used an unusual design to see how the results of the tensile test correlated with human use during anal intercourse. Men attending an STD clinic were provided 48 condoms each and asked to return their first used, unbroken condom and all the condoms that broke. Due to problems with recruitment, only 11 condoms from 10 different men that had been used during anal intercourse could be tested in the laboratory. Six of the condoms were unbroken and five broken. After being gamma-irradiated for infection control, the condoms underwent the tensile test, with results of the broken and unbroken condoms being virtually the same. Although results from such a small study are not statistically significant, the authors concluded that the tensile test was not sufficient to predict strong products. (Gerofi)

Unpublished Studies

In addition to the varying results from the published studies, the results of two unpublished studies by FHI add to the difficulty in reaching a clear conclusion about the predictive value of the laboratory tests.

One study initiated in 1994 examined four lots of condoms of the same age but in two different storage conditions. Two lots were stored in warehouses in Burkina Faso, a West African country with tropical conditions, and two lots were stored in the U.S. under ideal conditions. Of the 100 couples recruited for

this study, 76 used one condom each from the four condoms lots provided. The study compared the Condom Quality Index (CQI) and the condom breakage rates among the four lots. It tested the hypothesis that condoms with low CQI values would have higher condom breakage rates. As mentioned earlier, CQI is a numerical rating of condoms derived from a mathematical treatment of air burst volume measurements.

Measured prior to human use, the CQI values were 35 and 41 for the Burkina Faso lots and 60 and 79 for the U.S. lots. One would expect the lot with the lowest CQI to have the highest failure rate. Instead, the lots with CQI's of 35, 60 and 79 all had a failure rate of 5.3 percent, while the lot with a CQI of 41 had a slightly higher rate of 6.3 percent. The study indicated that the CQI alone was not a reliable predictor of condom functionality. (FHI 1994)

A subsequent FHI study sought to assess how well CQI values and other laboratory results predict condom functionality in human use. Three lots of latex condoms, each manufactured in 1990 by a different U.S.-based manufacturer, were evaluated in this study. Each lot was made of a latex formulation specific to its manufacturer. The three lots were divided into five sub-lots and packaged in either plastic or foil and lubricated with silicone or nonoxynol-9. Note that none of the published studies involving human use had attempted to isolate the variables of packaging and lubrication.

These five sub-lots were stored at FHI under ideal conditions and in three different locations in Mexico (Mexico City, Merida and Juarez). At approximately annual intervals, condoms from each sub-lot were sampled for laboratory testing. In addition, 125 couples were recruited annually to use the condoms stored at FHI and in Merida (worst storage condition among the Mexican sites). An analysis of the data after four years found that there was a slight upward trend in the breakage and total failure rates over time. The final

Methodological Challenges in Studying Condoms

by **Markus J. Steiner**

Studies of condom use have several major methodological challenges. These are particularly evident when trying to correlate actual condom use with laboratory tests. Such studies examine human behavior of an inherently private nature. Both user characteristics and types of sexual practices can affect condom failure.

Also, relating human behavior to laboratory tests involves evaluating the material integrity of the condom as it changes over time. Thus, studies comparing human use to laboratory tests involve people using condoms that could be of compromised quality, either from being artificially aged or from prolonged storage in poor field environments. In order to protect participants, the studies must be conducted among populations not at risk of STDs. Also, the couples who need protection against pregnancy must be using an effective non-barrier contraceptive method.

Couples participating in these studies usually receive some financial incentives. Since motivation to use condoms in the studies

is partly financial, research designs have each couple use an equal number of condoms from each lot to help control for valid responses regarding use.

Having each couple use an equal number of condoms from each lot also helps to control for the variation of sexual practices and user characteristics (such as penis size and vaginal dimensions) among different couples. Research has shown that some couples are more likely than others to experience condom breakage and slippage (see Chapter 3).

Controlling for variations of sexual practices within a single couple is virtually impossible, however. Even with the same partner, sexual acts may vary greatly from one episode to another. In order to assess the impact of variation in the sexual act on condom breakage rates, researchers have collected information on the intensity and duration of intercourse, and on sexual positions, through self-administered questionnaires. As with most self-reported information of a very private nature, this type of information cannot be verified objectively, making analysis problematic. Even so, such information is still valuable in attempting to shed some light on these factors.

report concluded that neither storage condition, packaging nor latex formulation appeared to influence these trends. (FHI 1996)

Conclusion

Which laboratory tests can best predict condom performance during human use? This research area lacks studies of sufficient size and rigor to be able to answer the question adequately. Another recent review of the literature, which included several unpublished studies, also concluded that the available data do not yet present a clear picture. (Enersol nd) While the studies have not provided a

definitive answer, they have contributed to the improvement of existing testing standards.

The 1992 FHI study was the first large-scale study that attempted to correlate results from the air burst and tensile tests to breakage rates in use. (Steiner) These two tests were considered the preeminent tests for measuring condom strength. As discussed above, in that study the age of the condom — not the air burst or tensile tests — correlated most closely with breakage.

Based on that study, USAID established a policy of monitoring condoms in the field that are two or more years of age and are still

stored at control or regional levels of the distribution system. USAID currently assesses the performance of these condoms using the air burst volume measurement, as well as the package integrity and lubricant quantity test. The published studies generally point toward using air burst volume measurements to monitor the natural aging process. The 1996 PATH laboratory study showed the importance of packaging and lubricants in contributing to the stability of condoms stored in adverse conditions.

Currently, as a practical approach for the field, the combination of age with the air burst, package integrity and lubricant tests is used to assess the quality of condoms in storage. This approach can provide some guidance for what combination of tests can be used on newly manufactured condoms to predict breakage problems. But future research should identify more specifically the predictive value of laboratory tests for newly manufactured condoms.

A greater understanding is emerging of how field conditions and human use interact with the chemical and mechanical properties of condoms. For example, recent laboratory studies and some small studies by manufacturers have focused increasingly on the importance of the stress and strain qualities of the latex formulation (see Chapter 4). The type of packaging, package integrity, and the type and quantity of lubricant have also emerged as critical issues to understand.

None of the studies discussed here has totally corroborated another. This lack of corroboration prevents the standards organizations from reaching consensus on which tests and what performance limits to require for new condoms, and has resulted in various standards and specifications being used throughout the world. Hence, regulatory agencies in many countries have been forced to choose which standard to adopt or to create an independent standard. This situation has become problematic, particularly for donor agencies and international manufacturers that

must adhere to the regulatory requirements of different governments.

Another variable is the quality of the laboratories used to test condoms. In many laboratories, condom testing is not the primary function and sometimes does not receive the level of attention needed to generate accurate and precise test measurements. Also, some laboratories have poorly designed and poorly maintained test equipment, with inexperienced or unqualified technicians. Only a few manufacturers of air burst test equipment distribute internationally, and the equipment is usually expensive, requiring skilled personnel and extensive preventive maintenance. Because of these costs, many laboratories are forced to design and construct their own test equipment and use unskilled labor. Testing consistency among laboratories has not improved to an acceptable level although some laboratories are working toward more uniformity through internationally sponsored inter-laboratory studies, including the USAID-sponsored CITNET effort (see Chapter 5) and work by the Enersol group in Australia.

Throughout this chapter, we have discussed the relationship between laboratory tests and condom failure during human use. Even if we could implement laboratory tests that are able to identify the most reliable condoms, this is only one step in the many efforts needed to ensure condom effectiveness on a societal level. Aside from condom quality, there are many other factors that determine the effectiveness of condoms, such as non-use and user behaviors (see Chapter 3). A recent overview of the condom literature developed what it called a "condom effectiveness matrix" to provide a way to consider these broader questions. (Spencer)

The predictive ability of existing tests can be summarized by what we know and what research questions we need to know more about.

What we know:

1. Latex condoms will degrade rapidly when not properly protected from heat, moisture or ozone.

2. Foil packaging is known to be superior to other packaging materials and is rapidly becoming the standard for latex condoms.
3. Latex condoms packaged in foil can remain reliable for use in excess of five years if package seals are not compromised and if the condoms have the proper formulation.
4. Taken together, air burst, package integrity and lubricant quantity testing are useful in evaluating the reliability of condoms stored in the field.
5. There is no single laboratory test that accurately predicts condom performance. Human use studies conducted thus far have not produced results that prove that any single existing laboratory test can be used as a surrogate for performance in use.

What we need to know more about:

1. What are the best laboratory test surrogates to use as predictors of performance in human use?
2. How do human sexual behaviors affect condom performance in use?
3. If properly packaged in foil, will condoms remain stable for five years (or more) in any environment, regardless of formulation?
4. Can laboratory tests predict the impact of variations in sexual behaviors on the condom?
5. Can we improve the precision among laboratories? Can inter-laboratory studies be designed to accomplish this?

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The Development of Non-latex Condoms

by Caroline E. Gilmore

The development of condoms made from other materials has been prompted by the epidemics of HIV/AIDS and other STDs, perceived shortcomings of latex condoms, the increasing incidence of allergies to latex condoms, and the advent of new technologies and materials. Various thermoplastic elastomeric materials have been tested, and designs and production techniques have been developed. As of 1997, the FDA had cleared (i.e., approved) five male synthetic condoms and one female synthetic condom for marketing. Several other male and female synthetic condom designs are under development.

This chapter describes the materials, designs, other product attributes and manufacturing processes of synthetic elastomeric male condoms; a synthetic elastomeric (polyurethane) female condom; and natural skin male condoms. It focuses on the condoms approved or under consideration by the FDA for marketing (see Table 7-1).

In the early 1960s, the FDA began requiring efficacy testing for medical devices. As the latex condom was already a proven method of protecting against pregnancy, it was "grandfathered" into the group of contraceptives approved without substantial clinical data on its effectiveness.

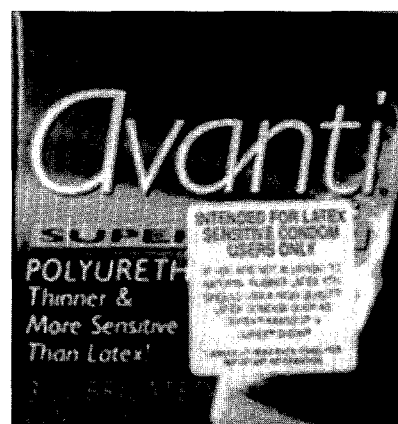
In the early 1990s, the FDA began requiring extensive clinical data before approving new medical devices. Hence, most new synthetic elastomer condoms are required to meet much more rigorous standards than latex male condoms. These clinical data requirements have delayed synthetic condoms

reaching the market. (Anonymous 1996) The Health Industry Manufacturers Association estimated that the application review time for new medical devices had more than doubled from 81 days in 1991 to 185 days in 1994. (Anonymous 1995) This review process is believed to be even longer now.

Synthetic Elastomeric Condoms

Research on new condoms has focused on synthetic compounds that are commonly called thermoplastic elastomers. The synthetic elastomeric condoms:

- may offer better physical properties than latex and may thus be stronger than latex
- transmit more body heat, hence allowing more sensitivity
- do not usually have an odor as does latex
- generally do not deteriorate with the use of oil-based lubricants and can thus be used with a variety of lubricants
- can be used by people who are sensitive or allergic to latex
- do not deteriorate under adverse storage conditions



Nash, Herndon/FHI

- are generally more uniform in their composition than latex, and
- can be formulated to feel like they are thinner than they actually are.

Under its substantial equivalence 510(k) submission process, the FDA has approved five synthetic elastomeric male condoms for marketing. Only one, the Avanti polyurethane condom manufactured by the London International Group, is currently commercially available. The others approved are two synthetic Trojan brand condoms by Carter-Wallace, Inc. and two Tactylon brand condoms from Sensicon (formerly known as Tactyl Technologies, Inc.). Other synthetic male condoms in the development stages are the Ezon condom, made of polyurethane by Mayer Laboratories, Inc., and a polyurethane condom by Ortho-McNeil Pharmaceutical of Canada.

Male synthetic condoms are currently approved by the FDA only for people who are allergic to latex. These condoms are required to have an interim labeling step until the required extensive clinical trials on contraceptive efficacy are completed. In the U.S., the Avanti package labeling currently states:

The risks of pregnancy and sexually transmitted diseases (STDs), including AIDS (HIV infection), are not known for this condom. A study is being done. There are laboratory tests on this polyurethane material. These tests show that organisms even as small as sperm and viruses like HIV cannot pass through it.

Male synthetic elastomeric condoms are manufactured using either a dipping process similar to latex condoms or a cut-and-seal process, which uses extruded synthetic elastomeric films. Currently there are three different types of synthetic elastomers being used: polyester polyurethanes, polyether polyurethanes and styrene-based elastomers.

Avanti Male Condom

Apex Medical Technologies developed the

initial design of a polyurethane male condom, then called the Sensation condom. The FDA approved it in March 1989, but the company never marketed it. Working with the London International Group, Apex amended the application, including design and formulation changes. The FDA gave pre-market clearance for this new design, now called the Avanti condom, in March 1991, ahead of a recent FDA ruling that manufacturers of medical devices be required to perform extensive clinical testing prior to marketing. Avanti entered the U.S. market in 1994 and is still the only synthetic male condom available for purchase there.

The Avanti condom is made from Duron, a thermoplastic elastomer in the polyester polyurethane family. The first version on the market, called the "Superthin" Avanti, had relatively high breakage rates in clinical studies conducted in 1994 by the Los Angeles Regional Family Planning Council (now the California Family Health Council), ranging from 4.4 percent to 15 percent. (Anonymous 1996) The high breakage rates may have been due to the thin film (0.037 to 0.042 mm). (For latex condoms, major standards and specifications vary: no requirement; minimum of 0.03 mm; minimum of 0.05 mm; and a range from 0.04 to 0.08 mm.)

A subsequent study compared a thicker version of the "Superthin" Avanti condom (0.045 to 0.050 mm) with a latex condom. The study found that the Avanti failed more often than latex, but the pregnancy rates of the two condoms were equivalent. For the Avanti, during intercourse and withdrawal, the breakage rates were 4.0 percent and slippage rates were 4.5 percent. Corresponding rates for the latex study control were 0.4 percent and 1.2 percent, respectively. The study did not address the comparable STD protection of the Avanti condom. (Nelson) Only this thicker version is being marketed.

The Avanti condom looks very similar to a straight-sided, reservoir-tipped latex condom. It is wider than the standard latex condom, measuring about 65 mm in lay-flat width

Table 7-1. Natural and Synthetic Condoms

	Natural		Synthetic					
	Male Latex	Male Skin	Male					Female
Brand Name	various	various	Avanti	Tactylon	Trojan	Ezon	NA	various
Manufacturer	various	Carter-Wallace, Inc. and London International Group	London International Group	Sensicon Corp.	Carter-Wallace, Inc.	Mayer Laboratories, Inc.	Ortho-McNeil Pharmaceutical of Canada	The Female Health Company
FDA clearance (approval)/year	various	various	yes/1991	yes/1994 (standard), 1997 (low modulus), pending (baggy)	yes/1995 (silicone lub), 1996 (N-9 and silicone)	no	no	yes/1993
Manufacturing method	dip mold	hand process	dip mold	dip mold	dip mold	NA	thermo-mold	extruded, die cut and heat sealed
Sheath material	latex	sheep cecum (lamb intestines)	polyester polyurethane (Duron)	styrene ethylene butylene styrene (Tactylon)	aliphatic polyurethane	NA	polyester polyurethane	polyether polyurethane
Retaining mechanism/material at open end	ring roll/rolled and pressed latex	elastic band encased in cecum fold glued or sewed to sheath	ring roll/extruded polyester polyurethane ring sealed in dipped polyurethane fold (Duron)	ring roll/rolled and pressed (SEBS)	integral ring roll/NA	two-layer flange or collar/NA	thermo-molded ring roll/NA	attached lower ring/pressed polyether polyurethane*
Approximate film thickness (mm)	0.01 to 0.10	variable	0.045 to 0.050	0.04 to 0.08	NA	NA	optimal: 0.01 to 0.10	0.042 to 0.055
Width/length (mm)	49 to 52/180	63 to 80/160 to 180	65/180	52 to 80/185	59/180	NA	NA	78 at widest diameter/170
Packaging	cellophane, foil, coated foil	plastic capsule, cellophane	foil	cellophane foil, coated foil	foil	cellophane	NA	cellophane
Pre-packaged lubricant	water-based, silicone, none	water-based	silicone	silicone, none	silicone	silicone	NA	silicone-based dimethicone**
Spermicide in lubricant	N-9, none	N-9, none	none	none	N-9	none	NA	none

NA – information not available

* The female condom also has an unattached ring inside the device at the closed end made of molded polyether polyurethane.

** Female condoms are sold with an additional water-based (glycerine) lubricant included in the package.

compared to the traditional 52 mm. A retaining ring is made from rolled, pressed polyurethane at the open end of the condom.

Tactylon Male Condom

Sensicon Corporation, a manufacturer of dipped and molded condoms and other medical products, has developed three new designs of male synthetic condoms. All the designs are made from a non-latex elastomer formulation of styrene ethylene butylene styrene (SEBS) called Tactylon, which was developed by Sensicon. Unlike silicone or polyurethane, SEBS can be formulated to mimic the elastic properties of latex.

Tactylon has similar elastic properties to latex but is translucent when non-lubricated and clear with silicone lubricant, compared to the tan, somewhat translucent latex condom. Tactylon condoms are manufactured with a vertical dipping process and have a minimal rim at the open end similar to latex condoms. The three designs are a standard condom, a "baggy" condom and a low-modulus standard condom, which is more elastic and has a higher elongation.

The standard design is cylindrical and nearly identical in specifications to currently marketed reservoir-tipped latex condoms. The FDA has cleared the marketing of the standard condom in both lubricated and unlubricated forms. It will be lubricated with silicone and packaged in foil. At least one form of this condom is expected to be on the market in 1998.

The more elastic, low-modulus design has an elongation in the range of 1000 percent (compared to the usual 800 percent elongation for male latex condoms). This greater elasticity may reduce the incidence of breakage during intercourse. The FDA has cleared this condom for marketing.

The "baggy" condom has an open end similar in lay-flat width (52 mm) to a traditional latex condom but a closed end with a much larger lay-flat width (80 mm). The larger

width of the baggy condom design may allow greater comfort and pleasure for users by reducing constriction and increasing frictional forces. At present, this condom design has not been cleared by the FDA for marketing.

Several studies have compared Tactylon and latex condoms for breakage rates and acceptability issues. A study using 250 standard Tactylon and 250 latex condoms found that the Tactylon condom performed as well and was as acceptable to users as the latex condom. (Trussell) In an FHI study comparing approximately 560 condoms of each of the three Tactylon designs with 560 latex condoms, the combined Tactylon breakage rates were slightly higher than the latex control. (Steiner)

Another study compared breakage and slippage rates of about 1,200 of each Tactylon design and about 1,200 latex condoms. The clinical breakage rates for the Tactylon condoms were higher than the latex control, which was 0.9 percent (far lower than most condom studies). The complete slippage rates were lower for the standard and low-modulus Tactylon condoms than the latex control (1.1 percent), while the slippage rate of the baggy Tactylon design was slightly higher. These data are from condoms used only during vaginal intercourse. Regarding acceptability issues, the standard and low-modulus condoms were significantly preferred to latex, with users noting enhanced sensitivity, sensation, fit and comfort. There were also fewer incidences of reaction and genital pain with Tactylon condoms compared to the latex control. The study, conducted by the Contraceptive Research and Development (CONRAD) Program, is not published.

Trojan Male Condom

Two variations of one design of a polyurethane male condom manufactured by Carter-Wallace, Inc. have been cleared by the FDA through the substantial equivalence 510(k) process: one condom lubricated with silicone

and one with N-9 and silicone. (Ohye) These condoms will most likely be marketed under the Trojan brand name.

The condom is manufactured through a dipping process of an aliphatic polyurethane material which results in a condom that has a higher tensile strength and break force than a latex condom. (Ohye) This condom measures 59 mm in width, 189 mm in length. Further details on this condom are not available from public records.

Ezon Male Condom

Ezon, a synthetic thermoplastic elastomeric condom developed by FHI, is to be manufactured and marketed by Mayer Laboratories, Inc. It has not yet received FDA approval. The Ezon condom is slipped onto the penis rather than rolled on and represents the first new male condom design since the traditional rolled-rim condom. The condom consists of a baggy sheath attached to a double-layered flange or collar at the open end. This flange is used for gripping and donning the condom and also serves as the retaining mechanism for the condom. The shaft of the condom is rolled up in between the double-layered flange and unrolls automatically as the condom is pulled on. The baggy design of the Ezon condom may increase sensation for men who feel constricted by a tighter-fitting latex condom.

The Ezon condom can be pulled on using either side, unlike roll-on condoms. It is easy to don, even in the dark, and reduces the interruption of putting on a condom. In contrast, a traditional roll-on condom can be put on correctly in only one direction. Additionally, beginning to don a traditionally rolled condom "inside-out" might contaminate it with bodily fluids. If this happens (and users suspect contamination with bodily fluids has occurred), it is recommended that a new condom be used, but many people simply reuse the original condom and thereby expose the vagina to the side of the condom that may have been contaminated with pre-ejaculatory

fluid. Further details on this condom are not available from public records.

Ortho-McNeil Thermoplastic Elastomer Condom

Ortho-McNeil Pharmaceutical of Canada, has developed a synthetic elastomeric condom, with a patent on the manufacturing method, the new condom and the use of the specific polyester polyurethane to make similarly shaped products. From diagrams, it appears that the condom consists of a contoured shaft, a reservoir tip and a rim roll made of solid polyurethane. The entire condom is made of a polyester polyurethane. The film thickness can be set from 0.005 to 0.24 mm, with optimal thickness of 0.01 to 0.10 mm. (Schut)

This condom is manufactured by a thermo-molding process. First, a ribbon of polyurethane measuring 1.0 to 1.9 mm is extruded. The ribbon is then pre-formed into a disk-like shape by a stamping process, then heated and further shaped. It is then re-heated and positioned along the rim of a mold cavity. A pressure plug, air pressure and vacuum are used in combination to draw the shaped polyurethane into the mold cavity without having the polyurethane touch the walls of the mold. (Schut)

The Female Condom

The female condom is manufactured and marketed by The Female Health Company. It was first marketed in Switzerland and the United Kingdom in 1992. In 1993, the FDA approved the condom for marketing in the U.S. The Female Health Company now holds worldwide rights to this condom design, which is manufactured in the United Kingdom.

The FDA has approved the female condom for the prevention of pregnancy and the prevention of STDs. In the U.S., the package labeling for the female condoms states:

Latex condoms for men are highly effective at preventing sexually transmitted diseases, including AIDS (HIV infection), if used properly. If you are not going to use a male

The FDA has approved the female condom for the prevention of pregnancy and the prevention of STDs.

latex condom, you can use the Female Condom to help protect yourself and your partner. Reality only works when you use it. Use it every time you have sex. Before you try the Female Condom, be sure to read the directions and learn how to use it properly.

As of 1997, the female condom had been marketed in about 20 countries, primarily in North America and Europe, although marketing efforts had begun in Brazil, Canada, Zimbabwe, Zambia and other African countries. It is marketed under various brand names including Reality in the U.S., Femy in Spanish speaking countries, the Care Contraceptive Sheath in Zimbabwe, and Femidom in other countries. WHO and the Joint United Nations Programme on HIV/AIDS (UNAIDS) have negotiated a price with The Female Health Company of less than U.S. \$1.00 per condom for the public sector in developing countries. This is helping to broaden its availability.

The female condom consists of a soft, loose-fitting, polyurethane sheath and a flexible polyurethane ring at each end. One ring, which is not attached to the condom, is placed in the closed end of the sheath and serves as an insertion mechanism and anchor inside the vagina. The other ring, which is attached to the open end, forms the external edge of the condom and remains outside the vagina after insertion, thus providing

protection to the labia and base of the penis during intercourse. Female condoms do not restrict the penis like most latex male condoms. As a result, sensitivity may be better for some couples. Additionally, since the condom covers the internal and much of the external genitalia, it may offer greater protection against the transmission of STDs than does the male condom, if used correctly. It can be inserted up to eight hours before intercourse.



A female condom.

The female condom is pre-lubricated with a non-spermicidal, silicone-based dimethicone lubricant and is generally sold with additional water-based, glycerine lubricant. The lay-flat width is about 78 mm at its widest diameter. Its length is approximately 170 mm and the film thickness ranges from 0.042 to 0.053 mm. The condom is packaged in cellophane.

The female condom is manufactured from an extruded polyether polyurethane film. The film is cut to shape and then sealed along the sides and closed end. The inner ring of the condom is manufactured by molding a polyether polyurethane similar to that used in the sheath of the condom. The outer ring at the open end of the condom is made from a pressed polyether polyurethane and is sealed to the sheath of the condom.

In more than 40 acceptability studies, a large proportion of women and men say they would use it if they could get it at an affordable price. However, the female condom currently is expensive and can be used only once. Researchers are investigating product integrity, safety and acceptability issues associated with multiple use of the female condom. Clearly, if safe and effective, multiple uses would reduce the effective cost of the device and thus make it more affordable to a wider range of couples. (FHI) The FDA approved shelf life is five years from date of manufacture.

Natural Skin Male Condoms

A natural skin condom is made from the cecum (a part of the intestines) of lambs. These condoms are loose-fitting on the penis and are supposed to conduct heat better than latex condoms and provide more sensitivity during intercourse. Because these condoms are made of natural membranes, oil-based lubricants may not be as damaging to them as they are to latex condoms. Natural skin condoms do not have reservoir tips.

The cecum is a blind pouch of intestine found near the opening of the large intestine there is only one cecum in each lamb. Lambs are the only plentiful domestic animals with

ceca that are the proper size and shape for a condom. The age of the lamb is also important, since skin condoms are too thin or tender if made from the ceca of very young lambs, and too thick or tough if made from the ceca of older lambs.

Ceca are removed from the lambs at the slaughterhouse and preserved in salt. Condom manufacturers then sort the fresh ceca and reject any that are too big, too small or damaged. The selected ceca are then cleaned of fats and debris by washing them with a caustic detergent. After washing, they are dried gently in hot air and are flattened. The membranes at that stage look like translucent parchment. A retaining device is needed to keep the condom on the penis because natural skin condoms are not elastic and simply drape around the erect penis. The retaining device is incorporated by placing an elastic band over the open end of the cecum and folding the lip of the cecum over the elastic band. The folded end is then sealed by either gluing or sewing. Once the elastic retaining ring has been added, the condoms are rehydrated and tested for quality assurance.

Because skin condoms are natural products, they do not conform to standard sizes as do synthetic condoms. Skin condoms range from 160 to 180 mm in length and 63 to 80 mm in lay-flat width. Skin condoms are packaged with a water-based lubricant designed to prevent the animal membrane from drying out. Skin condoms are sold in foil packets or hard plastic capsules and come in a rolled or a flat, unrolled form. (Brackett)

Natural skin condoms contain small pores that can measure up to 0.0015 mm across and have been shown in laboratory tests to permit the passage of hepatitis B virus, herpes simplex virus and HIV. However, they have been shown to prevent the passage of sperm and are considered effective contraceptives. The FDA permits natural skin condoms to be labeled only for the prevention of pregnancy and not for the prevention of STDs.

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Conclusion — What We Know and Research Priorities

by Erin T. McNeill

In recent years, condoms have come a long way. Today's condoms are largely reliable and effective, a powerful means to prevent pregnancy and disease if they are used regularly and correctly. The problem with condoms is not their effectiveness. Condoms are not being used as much as they need to be because of negative perceptions about condoms by users and potential users, by cultural and community leaders, by health-care providers and by policy-makers.

People do not like or trust condoms for a host of reasons. Many do not perceive that they are at risk of sexually transmitted diseases.

Others say condoms interrupt spontaneous sexual encounters or reduce desired sensation — it's like wearing your raincoat in the shower. Condoms can cause men to lose their erection, or they can suggest that you don't love or trust your partner. For

some, condoms are difficult to get or to use, or they have an offensive odor. And, some believe condoms are not reliable because they break and slip off. Some of these perceptions have more merit than others. Communication between partners about these issues occurs infrequently, contributing to non-use and allowing higher rates of STDs.

Cultural norms that define sexual behavior often preclude communication between

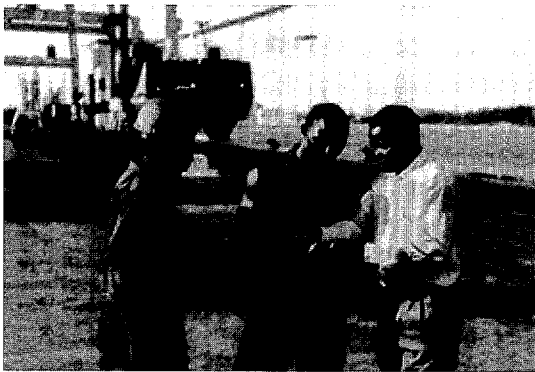
women and men about the desire and need to use protection, even when one partner is HIV-positive. A lack of action on the part of couples may reflect the views of those dominant in societies, often men, so that condom use is not yet even a legitimate part of sexual discourse. Those same social and cultural reservations in turn affect local and national policies, inhibiting access to condoms through public policy, unfavorable pricing, poor distribution, cautious information campaigns, and other barriers to making condoms readily accessible and desirable to use.

This monograph has shown the many reasons why policy-makers, program managers and users should have confidence in condoms today, if they are used consistently and correctly. The 10 most important reasons why we should have confidence in condoms, which emerge from the research findings presented throughout the monograph, are summarized on page 74.

Research Priorities

Given that most modern condoms are of high quality and can offer very reliable protection, it is disheartening that only about 5 percent of married women of reproductive age worldwide report using condoms as their current method of contraception, and only 3 percent of those in developing countries. In several countries where men have been surveyed about condom use, they report considerably higher ever-use and current-use rates than women do. This may be explained in part by the fact that men use more condoms exclusively for STD prevention or with extra-

Richard Lord



Health worker demonstrates to dock workers how condoms are used.

marital partners, or it may indicate men are over-reporting and women under-reporting condom use. Nevertheless, while it is very difficult to make accurate estimates of the overall number of people using condoms, there are undoubtedly millions leaving themselves at high risk of contracting a deadly disease, as rising HIV and STD incidences confirm.

Two priority areas for future research emerge from the data reviewed in this monograph: research to improve product attributes, and research to improve our understanding of acceptability and use. These are complementary domains, both of which will require the support and cooperation of public and private sector partners. Also, past and future research will achieve the greatest health impact if the results are shared with decision makers and condom users. Research priorities for both areas are summarized on page 78.

As this monograph has described, various physical attributes of condoms can influence how well the condoms function and how acceptable they are to users. Research and manufacturing advances in the product attributes themselves may increase satisfaction with condoms and overall use. Even more important is to learn much more about the complex aspects of sexual behavior that affect couples' motivation to use or reject condoms.

The quality of modern condoms is generally good. However, there are still some unresolved design, manufacturing and testing issues that, if fully understood, could lead to improved condom performance in use and greater acceptability to users. The priorities for research to improve product attributes are based on the recommendations of a 1996 expert meeting on latex condoms, convened by FHI at USAID's request, and on the findings presented in this monograph.

Product attributes play a minor role in condom acceptance compared to strategies that influence individuals' perception of the importance of using condoms and cultural norms which support their use. Donors, national programs, non-governmental organi-

zations and others carry the burden of protecting public health by providing, promoting and evaluating condoms.

Over the years a good deal has been learned from AIDS prevention campaigns about what works and what does not. The scare campaigns of the 1980s equating sex with disease and death were resoundingly unsuccessful. More recent research has demonstrated that sustained condom use is more likely if mass media and individual counseling focus on individual risk, taking positive responsibility for healthy sexuality and offering practical help to build condom use skills. Education and counseling efforts also have to be sustained over time. And, condoms are useful only if they are affordable, accessible and socially acceptable. The challenge in sustaining condom use leaves no room for complacency in public sector programs in particular and calls for more research to elucidate the details of human sexual interactions that impinge on condom acceptability and use.

Final Messages for Condom Users

People working in the reproductive health field including researchers, regulators, program managers, policy-makers and others need to keep the final goal in mind: consistent and correct use of high-quality condoms by those who need them. It is important to end with messages that users need to hear, through the programs that readers of this monograph might influence.

- Condoms have to be used correctly and consistently to work.
- Correct use is more complicated than it may seem because there are lots of ways to get it wrong. But if you learn how to use them well, condoms can be quite satisfactory.
- *Some users will* have difficulty using condoms successfully and will experience more than their share of breaks. Some of these

***Even more important
is to learn much
more about the
complex aspects of
sexual behavior that
affect couples'
motivation to use or
reject condoms.***

Continued on page 75

Ten Reasons Why We Should Have Confidence in Condoms

by Erin T. McNeill

1. When used correctly and consistently, condoms are an effective means of preventing pregnancy. Pregnancy rates for condoms range from 3 percent to almost 14 percent. This means 3 to 14 out of 100 women get pregnant in a year using only condoms for contraception. However, these pregnancies are not due primarily to condom failure. Higher pregnancy rates during typical condom use reflect inconsistent and incorrect use. Non-use, i.e., inconsistent use, is particularly dramatic. If a woman does not use a condom during just one fertile phase in a year, she has a four-times higher risk of becoming pregnant than if she uses condoms consistently and experiences occasional breakage. Moreover, the risk of breakage is concentrated in certain couples. This means that the majority of couples who use condoms consistently are at very low risk, at least of pregnancy.

2. When used correctly and consistently, condoms are an effective means of preventing STD/HIV. The equation is somewhat different for STDs than for pregnancy. The fertile period is intermittent, but individuals can be at risk of contracting an STD or HIV at every intercourse. Study after study has shown that condoms are extremely effective against STD/HIV if they are used consistently and correctly. In many cases couples do not know one another's HIV or other STD status. In these instances, not all partners are infected, and intermittent condom use will provide protection against transmission in a proportion of cases. However, if one partner is HIV-positive, then there is a *guaranteed* risk of

exposure to infection at every unprotected intercourse, and inconsistent condom use offers little protection against HIV, compared with non-use.

3. Latex condoms provide an impermeable mechanical barrier. Latex condoms are virtually impermeable to viruses and to sperm. Therefore, unless a condom breaks or completely slips off in a clinically significant manner, i.e. during or after ejaculation, or has a pinhole which is extremely rare, users are not exposed to semen or viral particles.* Broken or leaky condoms certainly expose women to semen and viruses, and expose men to infection from women, but on average, non-use of condoms exposes individuals to a far higher magnitude of risk.

4. Most users do not break condoms, and a proportion of breakage is preventable. Most people who use condoms, especially once they gain experience with them, rarely experience breakage or slippage; condom failure is actually concentrated among a small percentage of users. Studies have identified characteristics of condom users that seem to be associated with more frequent condom breakage and slippage. A history of condom failure and inexperience in using condoms are the characteristics most strongly associated with condom failure. Some research also suggests that young age, not living with one's sexual partner, low level of education, having multiple sexual partners, low income and large penis size are also correlated with increased risk of condom breakage and/or slippage.

Studies also suggest that certain behaviors are associated with increased breakage and/or slippage including: improper storage, rough handling of condoms, improper donning techniques, not encouraging natural vaginal

* During vaginal intercourse condoms only form a barrier between the skin of the penis and the skin of the vagina. Some sexually transmitted viruses such as HPV can be transmitted via skin-to-skin contact between the scrotal skin and the perineum. Therefore, even intact condoms cannot prevent the transmission of all organisms. Devices such as the female condom which cover more of the external genitalia may afford greater protection.

lubrication, using excessive added lubricants (especially oil-based), lengthy or vigorous sex, anal or oral intercourse, loss of erection prior to withdrawal, and re-use of condoms.

Since correct condom use is both a taught and a learned behavior, it is evident why these variables are related to condom failure, and how some might be reduced or prevented through improved education and counseling. Obvious problems like opening condom packages with sharp objects, and pre-stressing them by unrolling, stretching, or "water testing" before use can be avoided if condom users are told that such actions increase the chances of condom failure. Use of appropriate lubricant is also important to reduce the risk of breakage. Intensive one-to-one counseling of all condom users is not likely to be feasible, however, because it is labor intensive and expensive, so it remains a priority to identify the behaviors which most frequently lead to breakage and slippage and target broad education efforts at those.

Also, counseling may not help couples for whom condoms regularly break or slip off because he has a large penis, she has a small vagina, she has little vaginal lubrication, or their intercourse is especially vigorous or prolonged (although, counseling might at least

identify the nature of their problem with condoms). Some breakage may be prevented by using additional water-based lubricant during lengthy intercourse. Or the couple might be advised to extend foreplay until the woman is more aroused, or put on a new condom and discard the first one before intercourse is completed. Nevertheless, some anatomical challenges of using condoms might ultimately have to be overcome through improved condom design. We do not know whether these potential solutions have any merit because we have a very incomplete understanding of the detailed dynamics of human use of condoms.

5. Today's condom is manufactured with greater precision. An additional reason for users and reproductive health programs to have confidence in modern condoms is that latex condoms are better formulated, processed, finished and packaged than they have ever been in the past. During formulation there is now far greater control exerted over the chemical processes of oxidation and vulcanization, which reduces the risk of condom failure due to aging. Also, enough is known about the impact of condom modulus and stress and strain properties on performance during human use to enable manufac-

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problems can be addressed (e.g., rough handling of condoms, "pre-testing," re-use), but some may be harder to fix (e.g., penis size, type and length of intercourse, loss of erection).

■ While there may be better condoms in the future, for the time being latex is the best option, given price and availability.

■ Condoms manufactured in the developed world and many parts of the developing world are subjected to rigorous quality testing and are therefore quite reliable, especially if they are packaged in foil, the packet is intact, and they are within five years of manufacture.

■ There is no evidence that spermicidally lubricated condoms offer greater protection against disease or pregnancy than other condoms. In fact, the spermicide may cause one or other partner irritation and may put users at a greater risk of developing an allergy to latex. Therefore, it is best to use a condom that is lubricated with silicone or water-based lubricant. Oil-based lubricants should not be used with latex condoms.

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turers to optimize these properties by adjusting the latex formulation. In recognition of the growing problem of latex allergy, condom manufacturers make greater efforts to remove latex protein allergens during processing. Manufacturers are also aware of the potential risk posed from using talc as a dry lubricant and seem to have shifted to cornstarch. However, since cornstarch may not be entirely without risk, the search for a better and safer dry finishing powder continues.

6. Condoms use is improved by the right lubricant. Wet lubricants placed on finished condoms prior to packaging include water-based lubricants, alone or with spermicide added, and liquid silicone. The evidence suggests that using appropriate quantities of the right types of lubricant (in manufacturing and/or at the time of use) decreases breakage and increases satisfaction with condoms. Use of water-based lubricants may increase slippage, but data suggest that the protective effect against breakage may outweigh any risk of increased slippage.

There is no evidence that spermicidally lubricated condoms confer any advantage by increasing efficacy against pregnancy or disease, in spite of a consumer *perception* that spermicidal lubricant *ought to* do this. Condom marketing that promotes this misperception should be discouraged. Indeed, there is some preliminary evidence that spermicidal lubrication may promote leaching of latex allergens, thereby increasing the risk of allergy. Since spermicidally lubricated condoms also have a shorter designated shelf life, silicone is a preferable lubricant.

7. Condoms in intact foil packages last at least five years on the shelf. Recent data indicate that adequate packaging is crucial to the long-term integrity of latex condoms. Plastic packages expose condoms to greater and more rapid deterioration from oxidation, humidity, ozone and ultraviolet light than do foil packages. When properly sealed in foil packages, modern latex condoms are quite

resistant to adverse environmental conditions and will retain their quality for at least five years and probably longer. Thus all condoms should be packaged in aluminum foil, or foil-plastic laminate packages.

8. Production quality control and post-production quality assurance help ensure a reliable product enters the marketplace. In addition to many specific improvements in all aspects of latex condom manufacture, an extensive system of internal and external quality control and quality assurance is now in place to ensure latex condoms are of high quality. In the era of AIDS, the condom is considered a potentially life-saving medical device, and as such is subject to strict quality standards. Through both worldwide (the ISO) and regional standards bodies (the ASTM and CEN), minimum acceptable quality levels are set and enforced to permit manufactured products to enter the market. Some standards are enforceable by law, and others represent consensus guidelines.

In spite of the deliberate, and therefore often slow, nature of cross-national standard setting, there is now considerable uniformity across the three major standards agencies. Also, the world's two major procurement specifications, those of USAID and WHO, are the impetus behind additional measures designed to ensure product acceptability to service delivery programs and end users.

Neither standards nor specifications can protect condom users from poor quality devices that are manufactured without adequate quality assurance, or are tested in sub-standard laboratory facilities. However, the wide net cast by current standards bodies ensures that the great majority of condoms, in the majority of countries (including condoms supplied by international donors), are manufactured to a high standard.

9. While it is not yet clear how well the test standards predict results during human use, a combination of tests can provide clear guidance on the quality of condoms in the

field. The current battery of tests — condom dimensions, package integrity, lubricant quantity, water leakage, tensile properties, and air burst properties — assure that newly manufactured condoms conform to international standards and specifications. But uncertainty still surrounds the validity of these tests in assessing condom deterioration over time and predicting performance in human use.

For example, the tensile test provides valuable information on latex formulation and manufacturing uniformity, but because it measures a segment from the middle of the condom that is the least challenged during sexual intercourse, it is not a very good predictor of condom failure in human use. The air burst test, on the other hand, has accurately predicted human use breakage in some studies. In other studies, the age of the condom has been the best predictor of breakage. Unfortunately, good data are limited, and the few studies that have been done pre-date improvements in latex manufacture and packaging. Thus it is likely that new research would show less deterioration over time due to in-package oxidation and vulcanization, or poor package integrity.

For the time being, programs in the field wishing to assess possible condom deterioration posing a high risk of failure in human use will have to rely on a combination of condom age and the air burst, package integrity and lubricant tests. No single laboratory test is an adequate surrogate for condom performance during use.

10. Various synthetic alternatives to latex condoms show promise for expanding condom acceptability and use. In time, condoms made of synthetic materials may replace latex in part or altogether. Synthetic

condoms made from thermoplastic elastomers have several advantages over latex. They have more controllable physical properties such as strength and can be fashioned in any shape and size. They may transmit heat better than latex, allowing for greater sensitivity during intercourse. They usually do not have an odor, as latex can; do not deteriorate with oil-based lubricants; and do not produce allergic reactions. They are more uniform in composition than latex and may not deteriorate in the same way under adverse storage conditions.

Further, synthetic condoms can be designed for use by men or women — male or female condoms. This marks a genuine breakthrough for reproductive health programs because couples have a real alternative when negotiating whether or not to use a condom; they can use either type of condom. One study has shown that when both male and female condoms are offered as part of a safer sex strategy more sex acts are protected overall, by one or the other device.

Several non-latex male condoms have received FDA approval for marketing as hypoallergenic to latex, and one female condom has received approval for marketing for pregnancy and disease control as well. However, the only two currently being sold are the Avanti male condom (London International Group) and the female condom (Female Health Company). Even though alternatives to latex condoms may receive expedited FDA review and approval, the product development process is long and involved, and new products are slow to enter the market. Unfortunately, the limited availability and high cost of synthetic condoms relative to latex mean that most consumers are going to have to rely on latex condoms for the foreseeable future.

Recommended Research Priorities

by **Erin T. McNeill**

Research to Improve Product Attributes

■ **Research is needed to determine the optimal shape, size, modulus and thickness of condoms.**

More desirable condoms would cause less constriction of the glans, have lower modulus for strength and increased sensitivity, be more robust and able to withstand "heavy use" including vigorous, prolonged or non-vaginal intercourse, and be easier to put on and remove. Studies to determine consumer preferences for different condom designs and formulations must accompany these manufacturing modifications. Valid evaluations of variations in product attributes should be comparative, properly masked, and include different populations of users (such as those with and without experience). The goal is to develop affordable, high quality, condoms that couples prefer to use.

■ **Both the private and public sectors should continue to support research leading to the development and approval of male and female non-latex condoms.**

■ **Studies are needed to evaluate the best lubricants to use in the manufacture of condoms.** Evidence suggests that the right quantity, type and placement of lubricant is important for condom functionality, acceptability and safety. In addition, the added value and risk presented by spermicidal lubricants and by dry finishing powders (e.g. talc or corn-starch) should be critically examined.

■ **Maintaining and improving standards for quality assurance testing remains a priority.** Refinements in the test protocols for water

leakage, package integrity, and air burst tests are welcome for examination and validation. The more accurately these tests ensure a quality new product *and* predict success in human use the better. Industry should work with the public sector to develop additional tests that will better approximate the demands placed on condoms during human use, such as a meaningful coital model, and tests of pre-stress and fatigue.

Research to Improve Understanding of Acceptability and Use

■ **Further behavioral research on human sexuality is urgently needed.** Using more sophisticated qualitative methods can help distinguish the reasons why people are unprepared to try condoms from the reasons why people stop using condoms or do not use them correctly and consistently over time. The existing body of research has not gone far enough to tease apart these critical issues. The reasons given for non-use overlap with the reasons given for disliking condoms, and the most important ones have a great deal to do with the dynamics between sexual partners.

Women often assume that their partner will dislike the feel of a condom or fear the consequences of suggesting a condom because of implied infidelity, his or her own. Either partner may not use a condom, assuming it will not work or will break, or they are not at risk. And in the delicate circumstances of an unfolding sexual encounter, where the man often directs the script, he may dislike the feel or genuinely find a condom too tight, fear losing his erection, want to rush to penetration without adequate lubrication, or handle or use the condom roughly with the result that it breaks or slips and both partners lose confidence in it.

A more in-depth analysis of couples' actual experiences would identify the behaviors which

may be amenable to change through improved education and counseling. In addition, means could be sought to minimize the negative aspects of condom use and build condoms into scenarios of sexual excitement and mutual partner satisfaction.

■ **The role of mass media, marketing and other strategies, which encourage condom use, should continue to be examined.** FHI/AIDSCAP has distributed some 250 million condoms over the last six years, more than 85 percent of which were sold through social marketing. This impressive distribution has often taken place in the face of social strife, government or religious objections, and in environments of serious resource constraint. Thus marketing as a discipline, once permitted in a country, clearly addresses resistance to condom use.

Even so, we still do not understand what specific factors overcome cultural barriers in countries heretofore resistant to condom promotion, and in which media advertising and education campaigns were previously prohibited. Research is needed to evaluate the constellation of situational factors and other enabling conditions that overcome these barriers. In particular, what kind of information and education is needed by, and effective with, principal decision makers — government officials, religious leaders and service providers. These findings could then assist efforts at changing behaviors.

The success of mass media and social marketing is salutary. However, it is also important that these strategies not reinforce existing stereotypes about condom use and condom users. Several campaigns that have exploited stereotypes of male dominance and virility simply perpetuate negative gender norms. Parallel efforts to cultivate improved couple communication and negotiating power for women in sexual interactions are thereby undermined.

■ **We could learn more from successful condom users.** Qualitative studies that examine what characterizes a satisfied and accomplished condom user would supply useful information about the skills and personal and relationship attributes that lead to success. Existing data indicate that “experienced” users break condoms infrequently, while “inexperienced” users are prone to breakage. But they tell us little about what transforms the “inexperienced” into the “experienced.”

■ **We need to know more about the relative importance of counseling and mass marketing of condoms in terms of users' understanding of how to use them correctly.** With correct information and experience, condoms can be easy to use. However, data on the many ways in which people misuse condoms suggest that throughout the world many would-be users have an inadequate understanding of how to use them correctly. More research is needed into the most successful approaches to counseling and advertising, in terms of form and content, which lead to correct and sustained condom use. Likewise, more research is needed on the behaviors that contribute most frequently to condom failure.

■ **Condom distribution networks would benefit from increased knowledge of recent research findings about how to handle and store condoms to maximize their reliability.** Logistics managers should collaborate with service providers to develop systems to track condom failure in field conditions and correlate these with laboratory measures of quality.

■ **Sharing non-proprietary product information would be useful.** Useful information emerges from the condom industry's post-marketing surveillance of its condoms, especially related to user experience and satisfaction. Everyone would benefit from greater coordination among manufacturers and sharing of this type of information.

Acronyms and Abbreviations

AQL—acceptable quality level
ASTM—American Society for Testing and Materials
CEN—Comité Européen de Normalisation
CI—confidence interval
CITNET—Condom Inflation Test Network
CONRAD—Contraceptive Research and Development Program
CQI—condom quality index
CSW—commercial sex worker
DHS—Demographic and Health Surveys
FDA or USFDA—United States Food and Drug Administration
FHI—Family Health International
IPPF—International Planned Parenthood Federation
ISO—International Organization for Standardization
kPa—kiloPascals
L—liters
mg—milligrams
ml—milliliters
mm—millimeters
MPa—megaPascals
N—Newtons
N-9—nonoxynol-9
nm—nanometers
OR—odds ratio
PATH—Program for Appropriate Technology in Health
PSI—Population Services International
py—person-years
R²—correlation coefficient
STD—sexually transmitted disease
USAID—United States Agency for International Development
UV—ultraviolet
WHO—World Health Organization

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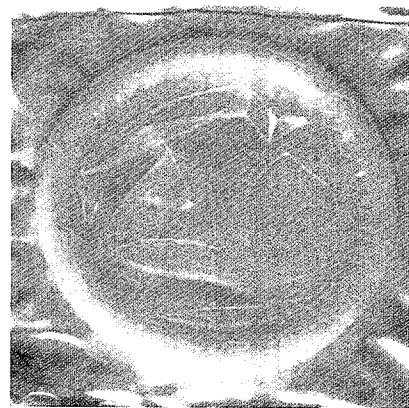
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